

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

OXYGEN CONCENTRATOR SERVICES



JUNE GIBBS BROWN
Inspector General

NOVEMBER 1994
OEI-03-91-01710

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Department of Health and Human Services

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EXECUTIVE SUMMARY

PURPOSE

This report describes the services provided to Medicare beneficiaries who rented oxygen concentrators in 1991. We conducted this study to determine the nature and extent of these services.

BACKGROUND

Medicare coverage of home oxygen care

Medicare allowances exceeded \$660 million in 1991 for oxygen concentrator rentals. Nationally, the average monthly allowance for stationary equipment including concentrators was approximately \$273.

Section 1861(S)(6) of the Social Security Act prescribes coverage of durable medical equipment (DME) including home oxygen equipment and supplies under Medicare. Medicare covers home oxygen care for beneficiaries who suffer from significant hypoxemia (a deficiency in the amount of oxygen in the blood). The Health Care Financing Administration (HCFA) manages the Medicare program.

Oxygen systems

The three primary oxygen systems are (1) oxygen concentrators, (2) liquid oxygen, and (3) gaseous systems. Liquid and gaseous systems are administered directly to patients using conventional tanks or cylinders.

Designed primarily for home use, oxygen concentrators are electrically powered devices which provide long-term, life-sustaining supplemental therapy for patients with inhibited pulmonary function, such as chronic obstructive pulmonary disease. The devices provide a richer concentration of oxygen to the patient by separating atmospheric gases from room air.

Concentrators require maintenance

The delivery of effective therapy embodied in home oxygen equipment implies that suppliers perform services on an initial as well as a continuing basis to assure the delivery of therapeutic care. Generally, patients using items such as wheelchairs and hospital beds require little monitoring. In contrast, oxygen therapy patients typically require more attention in the form of periodic services from the oxygen supplier. Such services may include equipment monitoring and maintenance, emergency service, and patient instruction and assessment.

The HCFA implemented changes in the processing of DME claims (including claims for oxygen concentrator rentals) effective October 1, 1993. Under the new system, suppliers must meet certain standards to obtain a billing number. However, the new standards did not delineate minimum service requirements for beneficiaries receiving home oxygen care.

Methodology

Using a 2-stage random sample, we selected beneficiaries in 8 Medicare carrier service areas. The 8 service areas (referred to as States in this report) were Arkansas, Georgia, Kentucky, New Jersey, North Carolina, Oklahoma, Pennsylvania, and Wisconsin. Our beneficiary sample represents the total population of 220,371 Medicare beneficiaries who received oxygen concentrator therapy for at least 3 months in 1991.

FINDINGS

Home Oxygen Concentrator Therapy Necessitates Support Services.

- ▶ Oxygen concentrator usage necessitates that suppliers deliver services periodically.
- ▶ A number of national organizations have established service standards for home oxygen care.
- ▶ Standards implemented by national organizations detail specific practices suppliers should meet, including guidelines for equipment and patient care.

Some Beneficiaries Receive Extensive Services While Others Receive Few Services.

- ▶ About 77 percent of beneficiaries do not receive equipment monitoring services every 30 days.
- ▶ Nearly half of all beneficiaries--47 percent--do not receive any patient care evaluations or assessments from suppliers.

Many Beneficiaries Did Not Receive Services Endorsed By National Organizations.

- ▶ Many of the beneficiaries did not receive the recommended services endorsed by two national organizations involved in respiratory treatment--the Department of Veterans Affairs and the American Association for Respiratory Care.

Medicare Policies Contribute To The Wide Variation In Support Services.

- ▶ Current Medicare policies do not delineate specific service requirements for suppliers providing home oxygen therapy.

- Beneficiaries may not be knowledgeable enough to select suppliers who provide appropriate ongoing services.

RECOMMENDATIONS

We recommend HCFA produce a strategy to ensure that Medicare beneficiaries receive necessary care and support in connection with their oxygen therapy. We offer a range of options for HCFA to consider which include (1) educating providers and beneficiaries about the kinds of services available and recommended by national organizations, (2) promoting industry standards to ensure better and more consistent supplier practices, and (3) setting minimum service standards by requiring suppliers to meet accreditation, certification, or licensing requirements.

COMMENTS

We solicited and received comments on our draft report from HCFA and other concerned organizations, which included the National Association for Medical Equipment Services (NAMES), the Health Industry Distributors Association (HIDA), the Health Industry Manufacturers Association (HIMA), and the American Association for Respiratory Care (AARC). The full text of their comments can be found in Appendix H.

The HCFA generally agreed with our recommendation, but preferred the first option we presented. The NAMES, HIDA, and AARC agreed with our recommendation and supported the establishment of more explicit service standards.

We appreciate the positive responses we received to our recommendation. Of all the reviewers who commented on our recommendation, HCFA was the most cautious in considering options for promotion of standards or setting minimum requirements. The HCFA believes that supplier business standards, newly in place, will address some of the problems we identified. While supplier standards can be used as a foundation for required services, they are neither explicit nor comprehensive in addressing the needs of beneficiaries on oxygen therapy.

The HCFA also expressed concerns about resources required to promote or set standards. While we appreciate these concerns, we believe that innovative approaches may be possible if HCFA pursues a productive partnership with concerned organizations, such as those which commented on our report. The HCFA may wish to explore these options in more detail with such organizations before committing to a specific course of action.

We also encourage HCFA to consider ideas beyond those which we have laid out, which might also accomplish the objective of ensuring beneficiaries receive needed services. Again, collaboration with industry and beneficiary organizations might identify some of those other approaches.

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INTRODUCTION

PURPOSE

This report describes the services provided to Medicare beneficiaries who used oxygen concentrators in 1991. We conducted this study to determine the nature and extent of these services.

BACKGROUND

Section 1861(S)(6) of the Social Security Act prescribes coverage of durable medical equipment (DME) including home oxygen equipment and supplies under Medicare. Medicare covers home oxygen care for beneficiaries who suffer from significant hypoxemia (a deficiency in the amount of oxygen in the blood). The Health Care Financing Administration (HCFA) manages the Medicare program.

The three primary oxygen systems are (1) oxygen concentrators, (2) liquid oxygen, and (3) gaseous systems. Liquid and gaseous systems are administered directly to patients using conventional tanks or cylinders.

On June 1, 1989, HCFA implemented a fee schedule reimbursement system for oxygen equipment. This replaced the customary, prevailing, and reasonable charge methodology process which governed DME reimbursements previously. The fee schedules set reimbursement rates in four categories: stationary equipment, oxygen contents, portable contents, and portable equipment. Within a carrier's service area, all items in each of the categories are reimbursed equally. The carriers developed the rates (subject to yearly updates) based on 1986 supplier charge data. Medicare allowances exceeded \$660 million in 1991 for oxygen concentrator rentals. Nationally, the average monthly allowance for stationary equipment including concentrators was approximately \$273.

Designed primarily for home use, oxygen concentrators are electrically powered devices which provide long-term, supplemental oxygen therapy for patients with inhibited pulmonary function, such as chronic obstructive pulmonary disease. The devices provide a richer concentration of oxygen to the patient by separating atmospheric gases from room air. Generally, patients qualify for oxygen concentrator therapy if they have reduced pulmonary function measurable by blood gas analysis or pulse oximetry testing.

Oxygen concentrators, unlike some other types of DME, deliver supplemental oxygen therapy directly to the patient. Patients using home oxygen may be too ill to leave their homes; many literally survive from day to day because of the therapy delivered by their oxygen equipment. Generally, patients using items such as wheelchairs, walkers, and hospital beds require little monitoring once their equipment has been delivered. In contrast, oxygen therapy patients typically require more attention.

Although HCFA states that these services are "an integral part of oxygen and DME suppliers' costs of doing business," the specific nature of these services is not delineated. The HCFA also states, "Such costs are ordinarily assumed to have been taken into account by suppliers (along with all other overhead expenses) in setting the prices they charge for covered items and services."¹

Changes in Claims Processing Environment

There have been concerns about past practices by some DME suppliers since Medicare's inception. Such practices include (1) carrier shopping (essentially, billing the carrier which has the highest reimbursement even though patients reside in a different area), (2) using multiple supplier billing numbers to disguise unethical billings, and (3) using telemarketing techniques to solicit supplies and equipment.

The HCFA implemented sweeping changes in the processing of DME claims (including claims for oxygen concentrators) filed on or after October 1, 1993. The changes were designed to counter abusive practices and streamline claims processing. The changes included the following:

- ▶ All existing suppliers had to reapply for Medicare billing numbers to a new entity known as the National Supplier Clearinghouse (NSC). Among other functions, the NSC investigates to assure that suppliers have only one billing number.
- ▶ The phasing in of four DME regional carriers (known by the acronym DMERCs) to process all DME claims as well as claims for orthotics and other medical supplies.
- ▶ Suppliers must meet specified standards to obtain a billing number, such as the repair and maintenance of rental items. (See Appendix A for a list of the standards.)
- ▶ Suppliers found not meeting standards could have their billing numbers revoked.

At the end of 1993, the supplier enumeration process under the new system was incomplete. About 75 percent of an estimated 120,000 DME suppliers had been enumerated, according to a HCFA representative.

Previous Office of Inspector General (OIG) Work

In 1987, we conducted a study comparing Medicare reimbursement for home oxygen and oxygen equipment with amounts paid by non-Medicare payers. We found non-

¹ Medicare Carrier's Manual, Section 5105.

Medicare payers had developed cost-effective reimbursement methods for home oxygen which resulted in monthly payments as low as one-quarter the amount paid by Medicare.

One of the non-Medicare payers mentioned in the report was the Department of Veterans Affairs (VA). We contacted 122 VA hospitals and found all paid substantially less than Medicare for home oxygen concentrators.

We found that VA hospitals have independent authority to decide which reimbursement options are the most economical. About 73 percent of the hospitals contacted provided home oxygen services through a competitive acquisition process.

We completed a study in 1990 centered on the medical necessity of oxygen concentrators for Medicare beneficiaries. Entitled "National Review of the Medical Necessity for Oxygen Concentrators," we reported that one-third of the sample beneficiaries in the study either did not need oxygen or did not need oxygen to the extent billed.

A follow-up study completed in 1991, "Oxygen Concentrator Reimbursement: Medicare and the Veterans Administration," revealed that Medicare pays more than twice as much for oxygen concentrators as the VA.

In another 1991 study entitled "Trends in Home Oxygen Use," we found that oxygen concentrators were the most frequently used home oxygen delivery system during 1989. Specifically, concentrators represented approximately 80 percent of Medicare payments for oxygen therapy services.

METHODOLOGY

Using a 2-stage random sample, we selected beneficiaries in 8 Medicare carrier service areas. The 8 service areas (referred to as States in this report) were Arkansas, Georgia, Kentucky, New Jersey, North Carolina, Oklahoma, Pennsylvania, and Wisconsin. Our original sample consisted of 275 Medicare beneficiaries representing 212 suppliers. These beneficiaries received oxygen concentrator therapy for at least 3 consecutive months in 1991, the most recent year available. Due to lack of supplier documentation, the final sample includes 183 suppliers representing 244 beneficiaries. This sample size allows us to project our results within +/- 1.2 percent to 12.3 percent at the 90 percent confidence level, with the great majority of estimates made within +/- 5 percent. Our beneficiary sample represents a total national population of 220,371 Medicare beneficiaries who received oxygen concentrator therapy for at least 3 months in 1991.

After we identified the suppliers who provided the oxygen concentrators, we wrote to them requesting copies of their records for the 1991 rental periods for the sample beneficiaries. We requested a copy of the original physician's prescription and copies of any written instructions supplied to the beneficiaries. We also asked each supplier

to complete a questionnaire detailing their company's background, staff qualifications, and practices on patient and equipment care.

Some beneficiaries received services from multiple suppliers during 1991. In these cases, we decided to use the information from the suppliers with the longest rental periods in our calculations. We did not attempt to determine why these beneficiaries had more than one supplier.

We accepted written evidence of home services rendered. When a supplier did not provide written evidence of services performed, we recontacted them to ask for such documentation. Twenty-nine suppliers representing 31 beneficiaries were unable to provide documentation. Reasons for lack of documentation include (1) no records could be found, (2) records were lost or destroyed, and (3) failure to document services performed. Since we were determined to use a conservative approach, we excluded these cases from our sample. Their exclusion reduced our sample size to 183 suppliers representing 244 beneficiaries. Still, our reliance on documentation is a limitation of our study since it is possible in some cases that services were rendered but not recorded. Likewise, services which were documented may not have been actually performed. Through follow-up calls with suppliers, visits with suppliers, classifications of services, and removal of suppliers with no documentation from our analyses, we attempted to minimize error in both directions.

We analyzed the information to determine the nature as well as the extent of services rendered in 1991. We classified the services as either an equipment or a patient monitoring service. Where documentation existed, we classified equipment set-ups as equipment monitoring services. (An example of one supplier's monitoring procedures is contained in Appendix B.)

Many suppliers submitted documentation on services which did not involve equipment or patient monitoring, such as disposable equipment drop-offs and equipment pick-ups. These services were not included in our classifications of equipment and patient monitoring services. (See Appendix C for examples of monitoring services.)

Patient education and training could be classified as either an equipment or a patient monitoring service. Since we found this service typically contains elements relating to patient care, such as assessing the patient's capacity to operate the device, we classified it as a patient monitoring service.

We contacted the oxygen supplier for clarification when we had questions about the type of service rendered. We gave suppliers the benefit of the doubt by giving them credit for performing a service if unresolved questions existed. A registered nurse with an extensive background in pulmonary care acted as our consultant and assisted us with the analyses.

We initiated the data calculations with a database of 244 beneficiaries. We divided the beneficiaries into **two subsets** of data: (1) those who had zero monitoring services,

and (2) those with one or more services. We then grouped beneficiaries by the number of billing months during 1991, from 3 to 12 months of service.

Some findings, such as the minimum and maximum number of days between services, are based upon the number of days between monitoring services. These findings could then be reported for those beneficiaries who had two or more services.

We based our analyses on a 30-day standard of service provision because suppliers bill Medicare and receive reimbursements on a monthly cycle. Therefore, the 30-day cycle with 60 and 90-day projections was both a logical and convenient standard to use to assess services provided to beneficiaries. (See Appendix D for an illustration of the calculations, statistical projections, and confidence intervals for percentages of beneficiaries.)

We visited a number of suppliers in different States to verify the validity of documentation and the credentials of supplier staff. We also contacted 22 beneficiaries to verify the type and frequency of services provided.

We contacted other third-party payers in the selected States, including VA hospitals, Medicaid State agencies, and private payers, to obtain their policies on services provided to oxygen patients. We also obtained information from the DMERCs and the NSC.

We met with a number of organizations, including the National Association for Medical Equipment Services (NAMES)², the American Association for Respiratory Care (AARC), the Health Industry Distributors Association (HIDA), the Health Industry Manufacturers Association, the National Board for Respiratory Care, ECRI (an organization which tests medical equipment and supplies), and the National Association of Medical Directors of Respiratory Care. The Food and Drug Administration provided additional expertise on pertinent pulmonary equipment and accepted respiratory care protocols.

Our review was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

²Formerly known as the National Association of Medical Equipment Suppliers

FINDINGS

HOME OXYGEN CONCENTRATOR THERAPY NECESSITATES SUPPORT SERVICES.

Oxygen concentrator usage in the home necessitates that suppliers deliver a wide array of services on a recurring basis. Oxygen use obligates suppliers to perform these services because of its relatively complex, clinical, and life-sustaining nature compared to most other DME devices.

The importance of support services, such as equipment and patient monitoring, for oxygen concentrator patients is critical for the proper functioning of the equipment as well as the effectiveness of the therapy it provides.

National accrediting bodies establish service standards for home oxygen care.

Accrediting bodies such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP) outline equipment and patient care standards. The JCAHO has accredited oxygen suppliers since 1988. In its 1993 manual, JCAHO requires oxygen suppliers to perform ongoing routine and preventive maintenance with qualified staff. Such maintenance must be documented. Approximately 27 percent of the responding suppliers maintained JCAHO accreditation. About 50 percent of the suppliers stated they were planning to seek accreditation in the future.

The CHAP also surveys and accredits home medical equipment companies. The CHAP stipulates that suppliers must utilize qualified individuals to provide patient education and training as well as periodic assessment of the equipment.

Professional organizations endorse service standards for home oxygen care.

Professional organizations such as the American Association for Respiratory Care (AARC) advocate specific guidelines in patient and equipment care. For example, one patient care guideline recommends that credentialed personnel:

- ▶ visit/monitor patients at least once a month, and
- ▶ assess patients, recommend changes in therapy, and instruct caregivers.

Equipment care guidelines recommend credentialed personnel:

- ▶ reinforce appropriate practices and performance by the patient and caregivers, and

- ▶ assure that the oxygen equipment is being maintained in accordance with manufacturers' recommendations.

The National Association for Medical Equipment Services (NAMES), which represents more than 2000 home medical equipment suppliers, has been active in promoting service standards for the oxygen therapy industry. In a Consensus Conference on Home Medical Equipment Services sponsored by NAMES in 1993, the attendees stressed the desirability of frequent, "regularly scheduled visits" for home oxygen patients. The workgroup advocated visits to stabilized concentrator patients every 30 to 60 days. The NAMES' Code of Ethics relating to services is in Appendix E.

Equipment manufacturers issue service manuals containing recommended maintenance activities for suppliers to perform at specified intervals. For example, DeVilbiss (model MC44-90) advises suppliers to check audible alarm systems and oxygen concentrations on a monthly basis. (See Appendix F for an example of maintenance recommendations.) Healthdyne (models H-300 and BX-5000) prescribes which maintenance functions should be classified by daily, weekly, monthly, and semi-annual time intervals.

Some organizations support the use of concentrators equipped with indicators or monitors. The indicators are warning systems to alert patients when the purity of the concentrator output falls below therapeutic levels. These groups include the American Society of Testing and Materials, a voluntary group which evaluates standards for medical equipment, and ECRI, an organization which tests medical devices.

Payers mandate service requirements for beneficiaries.

Payers, including the Department of Veterans Affairs (VA) and Medicaid State agencies, also delineate service requirements. The VA hospitals enter into legally binding contracts with their suppliers. The contracts set clear standards for items such as required equipment and accessories, patient education and training, frequency of visits, emergency care, documentation of services, and patient assessment by qualified staff. A typical example of required services is contained in Appendix G. (A separate report will compare Medicare reimbursements and standards to the VA as well as other third-party payers.) Georgia State Medicaid prescribes specific services which suppliers must provide at no additional reimbursement. Georgia Medicaid reimbursement for rental of concentrators includes disposable equipment necessary for operation, a monthly trip for checking the equipment, and patient training and instruction.

Some third-party payers (such as the Minnesota Medicaid program) mandate that suppliers only use concentrators with an indicator to monitor the concentrator output. Medicare has no policy on oxygen concentrator indicators or monitors.

SOME MEDICARE BENEFICIARIES RECEIVE EXTENSIVE SERVICES WHILE OTHERS RECEIVE FEW SERVICES.

We found variation in the delivery of equipment and patient services to beneficiaries. Some beneficiaries received extensive and periodic services, while other beneficiaries received services on an erratic basis.

Equipment monitoring services

Equipment monitoring services include checking concentration levels, changing and cleaning filters, and assuring the integrity of alarms and back-up systems.

Oxygen equipment must be maintained regularly to ensure the effectiveness of home oxygen therapy. Unclean filters, for example, can affect the purity of a concentrator's output resulting in less than therapeutic or even harmful therapy for the patient. Moreover, prolonged delivery of less than therapeutic levels of concentrator output can result in hypoxia (a reduction of oxygen in body tissues below normal levels). In severe cases, hypoxia leads to death of tissue cells. In less severe degrees, hypoxia causes depressed mental activity and muscle weakness. Clinically, such a patient exhibits decreased energy, shortness of breath, and cyanosis or a bluish skin discoloration.

As Table 1 indicates, 8 percent of the sample beneficiaries did not receive any equipment services. We projected this figure to the number of beneficiaries nationally. Of the 18,024 beneficiaries who did not get any equipment services, 65 percent had been renting oxygen concentrators for 6 months or longer.

Percent of Beneficiaries Receiving Equipment Services in 1991

Table 1.

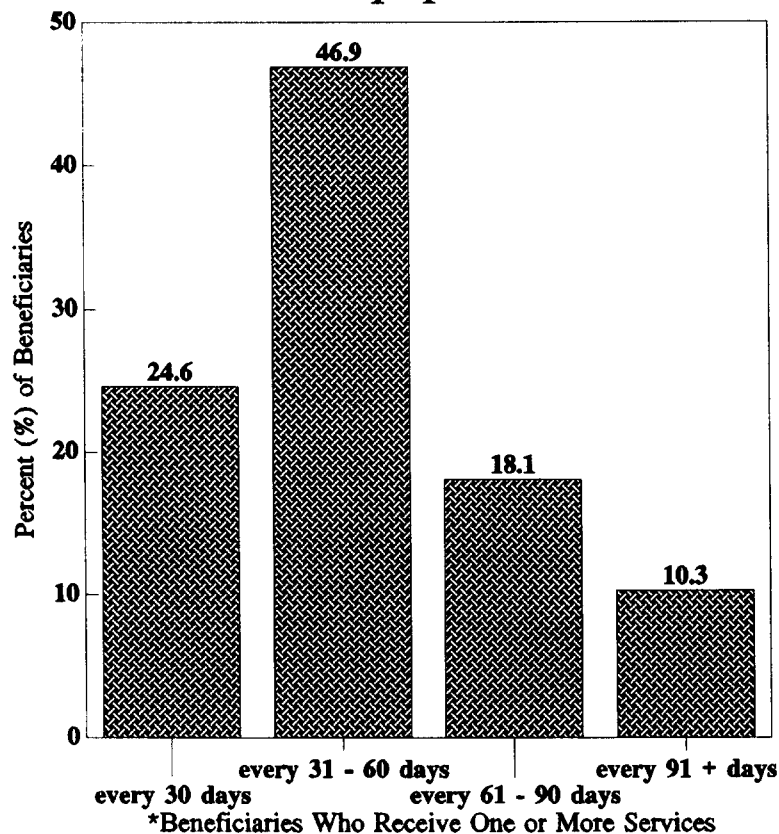
| | |
|--|-------------------------------|
| Beneficiaries With 0 Services | 8% 18,024 |
| Beneficiaries With One or More Services | 92% 202,347 |
| Total Beneficiaries Nationally | 100% 220,371 |

For the remaining 92 percent of sample beneficiaries who got one or more equipment services, we conducted further analyses. We calculated how often they received one service based on 30, 60, and 90-day cycles. These cycles correspond with the 30-day billing periods and various standardized time periods as advocated by many organizations involved in respiratory care.

As Graph 1 illustrates, about 25 percent of these beneficiaries received an equipment service every 30 days. Almost 47 percent received a service every 31 to 60 days. Another 18 percent got one service every 61 to 90 days, while 10 percent received an equipment service every 91 or more days.

Graph 1.

How Often Beneficiaries Received One Equipment Service*



To display the variation in the amount of time between equipment services, we examined the number of days between services for beneficiaries who had two or more services. We grouped the beneficiaries by the number of months they had been using oxygen therapy. As Table 2 indicates, a wide range in the number of days between services exists in each billing category. For example, one beneficiary who used oxygen therapy for 12 months waited 223 days between equipment services, while another beneficiary who also used oxygen therapy for 12 months received an equipment service 2 days following a previous service. This variation exists in each of the billing categories.

Maximum and Minimum Number of Days Between Equipment Services*

Table 2.

| Number of Billing Months for Beneficiaries | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|----|----|-----|----|-----|----|-----|-----|-----|-----|
| Highest Number of Days Between Equipment Services | 58 | 62 | 108 | 84 | 109 | 91 | 237 | 153 | 136 | 223 |
| Lowest Number of Days Between Equipment Services | 5 | 3 | 1 | 10 | 10 | 14 | 6 | 12 | 16 | 1 |

*Includes Only Beneficiaries Who Received Two or More Equipment Services

Patient monitoring services

Although Medicare does not provide additional reimbursement for clinical patient services in home oxygen care, many suppliers provided these services and evaluations along with equipment monitoring services. Examples of patient monitoring services include taking vital signs, testing pulse oximetry, instructing the patient in proper self-care as well as routine equipment care, and evaluating symptoms such as breath sounds, sputum production, and skin color.

Nearly half (47 percent) of the sample beneficiaries received no patient services, as shown in Table 3. This percentage represents 102,665 beneficiaries nationally. Of these beneficiaries, almost three-quarters were on oxygen therapy for 6 to 12 months.

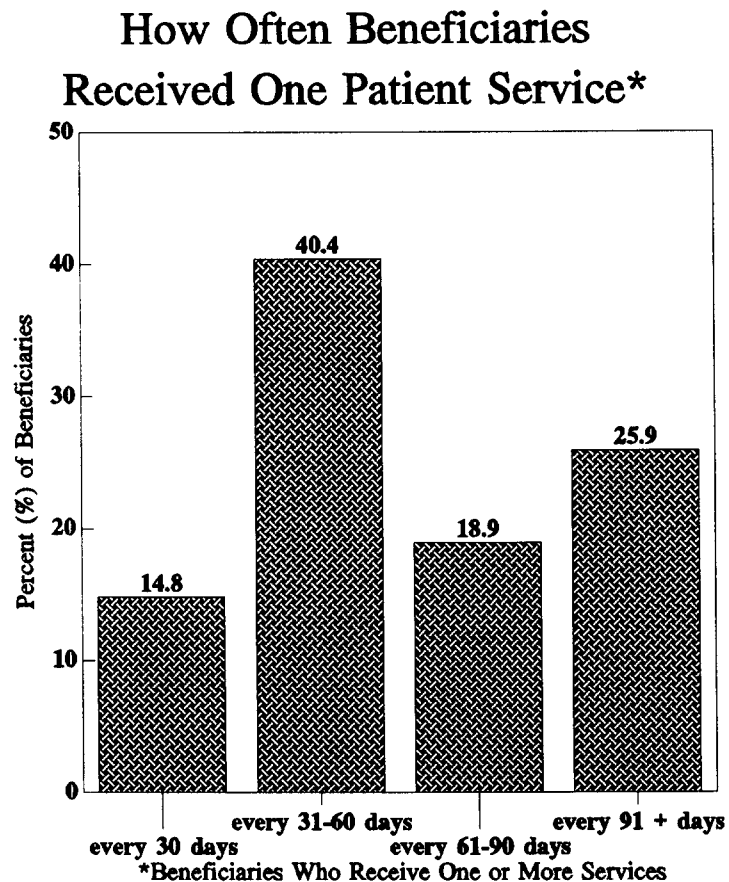
Percent of Beneficiaries Receiving Patient Services

Table 3.

| | |
|---|-----------------|
| Beneficiaries With 0 Services | 47% 102,665 |
| Beneficiaries With One or More Services | 53% 117,706 |
| Total Beneficiaries Nationally | 100% 220,371 |

For the remaining beneficiaries who got one or more patient services, we calculated the frequency of services based on 30, 60, and 90-day cycles (refer to Graph 2). About 15 percent of these beneficiaries received one service every 30 days. Forty percent of these received one patient service every 31 to 60 days, while about 19 percent had one patient service every 61 to 90 days. Approximately 26 percent received one patient service every 91 days or more.

Graph 2.



As with equipment services, the time between patient services varied widely. We calculated the amount of time between patient services for beneficiaries who received two or more services. We arrayed these beneficiaries according to the number of months they had been using oxygen therapy. As Table 4 shows, a wide range in the number of days between services exists within each billing category. One beneficiary who had been on oxygen therapy for 12 months waited 334 days between patient services, while another beneficiary, who had also used oxygen for the entire year, received a service one week following the previous service.

Maximum and Minimum Number of Days Between Patient Services*

Table 4.

| Number of Billing Months for Beneficiaries | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|----|----|----|----|-----|----|-----|----|-----|-----|
| Highest Number of Days Between Patient Services | 49 | 55 | 51 | 82 | 106 | 92 | 190 | 86 | 111 | 334 |
| Lowest Number of Days Between Patient Services | 5 | 12 | 1 | 7 | 4 | 2 | 6 | 25 | 22 | 7 |

*Includes Only Beneficiaries Who Received Two or More Patient Services

MANY BENEFICIARIES DID NOT RECEIVE SERVICES ENDORSED BY NATIONAL ORGANIZATIONS.

Many beneficiaries in our sample did not receive equipment or patient care as specified in guidelines advocated by national accrediting bodies, professional organizations, and third-party payers.

Equipment service guidelines for 77 percent of the sample beneficiaries did not meet the standards set by the VA and AARC, both of whom recommend monthly equipment monitoring services.³ We found 34 percent of the sample beneficiaries did not receive services according to NAMES' standard, which advocates one equipment service every 60 days. As Table 5 indicates, the percentages represent a projected number of beneficiaries in the nation who did not receive equipment services according to national standards set by these organizations.

Ninety-two percent of the sample beneficiaries did not receive the patient care services recommended by the VA and AARC, which advocate a patient monitoring service every 30 days. About 70 percent did not meet NAMES' guidelines, which recommend a patient service every 60 days.

³ To calculate the figures for Table 5, we first added the number of projected beneficiaries who received zero services and the projected number of beneficiaries with one or more services who fell into appropriate 30-day cycles. We then divided this sum by the total beneficiary population.

**Percent of Beneficiaries Whose Oxygen Therapy Services
Did Not Meet Recommended National Standards***

Table 5.

| Source | Standard | Equipment Services | Patient Services |
|--|----------------------------|-------------------------------|-------------------------|
| Department of Veterans Affairs | 1 service every 30 days | 77.4% 170,535 | 92.1% 202,911 |
| American Association for Respiratory Care | 1 service every 30 days | 77.4% 170,535 | 92.1% 202,911 |
| National Association for Medical Equipment Services | 1 service every 60 days | 34.3% 75,602 | 70.5% 155,412 |

***Total population of Medicare beneficiaries nationally who use oxygen concentrators in 1991=220,371.**

Many suppliers cited various reasons for not providing services. One supplier reported that he occasionally "overlooks" patients. He encouraged patients to contact his company if no visits had been made for a couple of months. We contacted another supplier who had not submitted any documentation and asked if this was an inadvertent omission on his part. The supplier said the beneficiary lived too far away to visit and stopped by occasionally to pick up filters and tubing to do his own maintenance. These practices conflict with JCAHO guidelines which recommend periodic maintenance services conducted and documented by a qualified person.

**MEDICARE POLICIES CONTRIBUTE TO THE WIDE VARIATION IN
SUPPORT SERVICES.**

We believe that the lack of standards or financial incentives for support services in 1991 contributed to the wide variation in services which our analysis found. Since there were no mandatory standards for suppliers set by Medicare and no payment consequences for different levels of service, both the quality and quantity of services to Medicare beneficiaries differed from one supplier to another.

Even though HCFA implemented business standards as part of its new claims processing system, they have not detailed specific service requirements for beneficiaries receiving home oxygen therapy. There are no provisions regarding type or frequency of services that should be rendered, record-keeping practices, emergency care, patient education, home safety assessments, or infection control practices. Further, neither the supplier nor the supplier's staff are required to meet minimum licensing, certification, training, educational, or credentialing standards.

The variation in levels of services to beneficiaries also demonstrates a payment inequity among suppliers. Some suppliers provide regular ongoing service, while others do not. Although Medicare reimburses fixed payments to oxygen suppliers

within designated geographic areas, the levels of services provided to beneficiaries residing in these areas varies considerably. Thus suppliers providing necessary services, as delineated by national accrediting bodies, professional organizations, and many third-party payers, are placed at a competitive disadvantage. Beneficiaries may not be knowledgeable enough in many cases to distinguish between "high service" suppliers and "low service" suppliers. For example, one DMERC official reported that some Medicare beneficiaries believe they have to assemble the oxygen concentrator by themselves. The HCFA has no recourse against a company providing minimal or sporadic services because it has not adopted service standards against which to measure supplier practices.

RECOMMENDATIONS

We recognize that our data represents the state of care provided by suppliers to Medicare beneficiaries in 1991, and concerned organizations have implemented improved standards of care since then. Nonetheless, it seems clear that Medicare policies could better support those efforts.

WE RECOMMEND THAT HCFA PRODUCE A STRATEGY TO ENSURE THAT MEDICARE BENEFICIARIES RECEIVE NECESSARY CARE AND SUPPORT IN CONNECTION WITH THEIR OXYGEN THERAPY.

We offer several options for HCFA to consider when developing this strategy: educating providers and beneficiaries, promoting standards, or setting minimum service requirements for Medicare suppliers. These options are not meant to be exhaustive or prescriptive; rather, they serve as an indication of the range of possibilities available to HCFA in developing its strategy.

Educating Providers and Beneficiaries

The HCFA could initiate a program to educate providers and beneficiaries about the kinds of services available and recommended by national organizations for patients receiving oxygen therapy. Such an educational initiative might be most effective if undertaken in partnership with relevant professional associations. This could include these options:

1. Educating health professionals (physicians, hospitals, etc.) to question, seek out, and refer patients to suppliers providing recommended services. This could be accomplished through articles in intermediary and carrier newsletters and bulletins directed towards providers.
2. Informing beneficiaries of the kinds of services they should look for from their suppliers. This could be achieved by including a section in HCFA's **Medicare Handbook** on oxygen services, inserting educational messages on the Explanation of Medicare Benefits (EOMB) form, or using the expertise of Peer Review Organizations or Information Counseling and Assistance Grants to reach out to beneficiaries receiving oxygen therapy.

Educational initiatives directed to providers and beneficiaries would likely be the least onerous option available to HCFA. With consumer education, suppliers providing higher levels of service should receive more Medicare business. As a result, more beneficiaries would receive higher levels of care and their oxygen therapy would likely be more effective and therapeutic.

Promoting Standards

The HCFA could promote standards for oxygen therapy services which suppliers should provide to Medicare beneficiaries. For example:

1. The HCFA, perhaps with the assistance of the DMERCs, could take a leadership role in promoting the standards endorsed by JCAHO, CHAP, NAMES and other concerned organizations to the Medicare supplier community.
2. The HCFA could develop payment policies which provide financial incentives for suppliers meeting specified standards. This could be accomplished in a number of ways. Suppliers who are not accredited, for example, could receive a different reimbursement from Medicare from those which are not accredited. Another option could be to designate accredited suppliers as "preferred providers" for purposes of referrals for Medicare business.

Promoting industry standards is just another way to encourage better and more consistent practices among suppliers. This is more likely to be effective if linked to Medicare reimbursements or the flow of referrals in some way; however, this approach would add a layer of administrative responsibility for the program.

Setting Minimum Requirements

The HCFA could establish a minimum level of service requirements for suppliers. This could be accomplished and enforced through a number of mechanisms. For example, any one or a combination of the following strategies could be used:

1. Accreditation -- The HCFA could require suppliers to become accredited by a nationally recognized organization such as JCAHO or CHAP.
2. Certification -- Many suppliers meet accreditation requirements but, for financial or other reasons, have not undergone an inspection process to become officially accredited. In these cases, suppliers could certify (see below) that they meet all such requirements.
3. Licensure -- We have not surveyed States to determine what licensing requirements might be placed on DME suppliers in certain States. We do know, however, that in some States suppliers must be licensed by the agency which regulates pharmacies. It may be that State licensure could be a vehicle to derive minimum standards, although a model licensure law developed by the Federal government might be necessary for this approach to be effective.

Suppliers could certify annually to their DMERCs that they meet one or more of the proposed alternatives--accreditation, certification, or licensure. Suppliers found to be misrepresenting information in their certifications would have their billing numbers

suspended. The HCFA could ensure compliance through random checks, beneficiary surveys, and investigations of beneficiary complaints.

Although this is the most demanding of the options we present, we believe it provides HCFA with the most assurance that standards are being consistently met by all suppliers. Additionally, it gives HCFA authority to require corrective action from suppliers found to be providing substandard or inappropriate care.

COMMENTS ON OUR REPORT

We solicited and received comments on our draft report from HCFA and other concerned organizations, which included the National Association for Medical Equipment Services (NAMES), the Health Industry Distributors Association (HIDA), the Health Industry Manufacturers Association (HIMA), and the American Association for Respiratory Care (AARC).

The full text of their comments can be found in Appendix H. A summary of comments and our response follows.

HCFA

The HCFA agreed that suppliers should provide necessary services in connection with the oxygen equipment and supplies they furnish. The HCFA concurred with our first option to educate providers and beneficiaries about the kinds of services available and endorsed by national organizations. They also provided examples as to how the education could be implemented. The HCFA felt our other options would not be feasible because of anticipated administrative burdens. Rather than promoting new standards and accreditation, however, HCFA indicated that the existing supplier standards could be used to ensure improved service to beneficiaries. As an example, HCFA said that a supplier that does not follow the equipment manufacturer's maintenance procedures would be in violation of the standards. The HCFA will continue to encourage the DMERCs to review suppliers for compliance with Medicare requirements and standards.

NAMES

The NAMES supports our recommendations for increased supplier and beneficiary education along with industry standards to enhance the level of services. The NAMES also stressed its commitment to promoting service standards in the industry, encompassing minimum supplier service standards and supplier and beneficiary education. Further, NAMES volunteered to work with HCFA to develop specific supplier standards.

The NAMES questioned some of the findings based on the age of the data and the supplier sample. They believe the industry has moved consistently and aggressively to becoming more service oriented. According to NAMES, JCAHO accreditation was in

its infancy in 1991; relatively few suppliers had been accredited at that time. Today, more than 1400 suppliers have received JCAHO accreditation.

The NAMES also took the position that our inclusion of past industry abuses and prior studies was not relevant to the purpose and objectives of the current study. The NAMES also made a number of technical comments.

HIDA

The HIDA agreed with our conclusions concerning inconsistency among suppliers with respect to the level of services provided to oxygen patients. In addition, HIDA voiced support for our recommendation option to establish strong supplier standards. The HIDA said that defining standards of service would result in the provision of the highest levels of service and care for Medicare beneficiaries. The HIDA advocates different levels of standards based on the type of services a supplier provides, such as basic standards for traditional DME or more stringent standards for patients receiving ventilator care or home infusion therapy. The National Supplier Clearinghouse could be the entity to develop and monitor stronger standards, according to HIDA.

The HIDA felt our recommendation option relating to different payment amounts tied to which suppliers who do or do not meet standards requires further analysis. In particular, HIDA thought that we should consider levels of service from the patients' needs in addition to suppliers' capabilities. Additionally, HIDA made a number of technical comments.

HIMA

The HIMA provided brief comments on the draft report. Oxygen therapy should be characterized as "supplemental" oxygen rather than "life supporting," according to HIMA. The HIMA pointed out that FDA considers oxygen concentrators to be "non-life" support devices which provide supplemental oxygen. In our recommendation option on establishing minimum requirements, HIMA felt that HCFA should also require monitors or indicators which are devices which signal concentrator failure. Furthermore, the absence of monitors or indicators should result in less reimbursement than units which include such devices. Some industry equipment standards require that monitors or indicators be included as part of concentrator equipment, according to HIMA.

AARC

The AARC agreed with our findings and recommendations. The AARC stated that support services, in particular, patient assessment, is a key element of home oxygen therapy. Furthermore, inconsistencies in providing such services among suppliers cannot be permitted. Until minimum service standards are mandated by HCFA, inappropriate care will abound, AARC added.

The AARC expressed concern about some aspects of the report. For example, AARC felt the sample size was too small and could affect the statistical validity of the report. Furthermore, they said that broad comparisons are made between Medicare and the VA. They suggested that we emphasize the differences between the Medicare program and the VA program instead of broad comparisons. The AARC also included some technical comments in their response.

OIG RESPONSE

Recommendation

We appreciate the positive responses we received to our recommendation. Of all the reviewers who commented on our recommendation, HCFA was the most cautious in considering options for promotion of standards or setting minimum requirements. The HCFA believes that supplier business standards, newly in place, will address some of the problems we identified. While supplier standards can be used as a foundation for required services, they are neither explicit nor comprehensive in addressing the needs of beneficiaries on oxygen therapy. The HCFA also expressed concerns about resources required to promote or set standards. While we appreciate these concerns, we believe that innovative approaches may be possible if HCFA pursues a productive partnership with concerned organizations, such as those which commented on our report. The HCFA may wish to explore these options in more detail with such organizations before committing to a specific course of action. We also encourage HCFA to consider ideas beyond those which we have laid out, which might also accomplish the objective of ensuring beneficiaries receive needed services. Again, collaboration with industry and beneficiary organizations might identify some of those other approaches.

Technical Comments

In response to questions about the size of our sample, we have expanded on our explanation of the confidence intervals for the sample and also refer readers to Appendix D, which provides more details on our projections and their precision. We also have acknowledged in this final report, as we did in the draft, that the data is based on 1991 claims and services and that our findings relate to Medicare beneficiaries' experiences in that year. In fact, we have prominently acknowledged that concerned organizations have worked to develop guidelines and standards since that time. Nonetheless, Medicare policy could better support these efforts.

While we understand NAMES' comment that prior work on the general topic of oxygen therapy might not be of specific relevance to these findings or recommendations, we believe that many readers will be interested in the prior work of the OIG on this general subject. As a result, we have retained this discussion.

Likewise, while we understand AARC's concerns about broad comparisons between the VA and Medicare and agree that there are certainly differences between the

programs, the scope of our inquiry is necessarily at a more general level. In this study, the VA standards represent one of several points of comparison to Medicare experience. Consequently, we have also retained this discussion.

Finally, in response to other technical comments we received, we have made a number of changes in the report to clarify or correct the use of terms.

APPENDIX A

MEDICARE SUPPLIER STANDARDS

1. In response to orders which it receives, a supplier must fill those orders from its own inventory or inventory of other companies with which it has contracted to fill such orders or fabricates or fits items for sale from supplies it buys under a contract.
2. A supplier is responsible for delivery of Medicare covered items to Medicare beneficiaries.
3. A supplier honors all warranties, express and implied, under applicable State law.
4. A supplier answers any questions or complaints a beneficiary has about an item or use of an item that is sold or rented to her or him, and refers beneficiaries with Medicare questions to the appropriate carrier.
5. A supplier maintains and repairs directly, or through a service contract with another company, items it rents to beneficiaries.
6. A supplier accepts returns of substandard (less than full quality for particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and/or sold) from beneficiaries.
7. A supplier discloses consumer information to each beneficiary with whom it does business, which consists of a copy of these supplier standards to which it must conform.
8. A supplier complies with the disclosure provisions cited on the HCFA-192 form.*

* Refers to the disclosure of ownership and control information by the supplier business entity on the enrollment and application form for a Medicare billing number.

APPENDIX B

ONE SUPPLIER'S MONTHLY CHECKLIST FOR OXYGEN CONCENTRATORS

- ☐ Clean exterior of unit
- ☐ Clean or replace filters
- ☐ Clean interior of unit
- ☐ Check for signs of overheating*
- ☐ Check foam for proper placement and deterioration
- ☐ Check fan for proper operation
- ☐ Check unit for leaks
- ☐ Check system pressures
- ☐ Check cycle time
- ☐ Check outlet pressures and temperatures
- ☐ Check unit for proper air flow
- ☐ Read concentration at maximum liter flow
- ☐ Read concentration at prescribed liter flow

* Signs of overheating can be heat dots on sieve beds, changing color, yellowing and cracking of fittings warpage of plastic parts, etc.

APPENDIX C

EXAMPLES OF CLASSIFICATION OF MONITORING SERVICES

Examples of Equipment Monitoring Services:

- Changing Filters
- Cleaning Filters
- Checking the Oxygen Flow Rate
- Checking the Back-up System
- Cleaning the Cabinet
- Checking the Concentrator Purity (percentage)
- Concentrator Service/Check
- Service Call

Examples of Patient Monitoring Services:

- Reports on the Condition of the Patient
- Pulse, Blood Pressure, etc.
- Patient Checklist to Ensure Understanding of Equipment and Care
- Phone Calls to the Patient Which Include In-Depth/Comprehensive Patient Care Questions

Equipment Set-Ups Classified as an Equipment Monitoring Service:

Included When:

Clear Set-Up Documentation/Matches with Billing Start Date

Not Included When:

No Set-Up Documentation is Found

Already Classified as a Separate Equipment Service

No Documentation of Any Service, Despite Billing Dates

Examples of Equipment Drop-Offs:

- cannulas
- humidifiers
- tubing
- water-traps
- trachea trays
- E-tanks
- D-tanks
- H-cylinders
- Refills (liquid)
- Portable Equipment Not Counted
- Nebulizers and Drugs Not Counted

APPENDIX D

CALCULATIONS AND CONFIDENCE INTERVALS

Calculations of the Number of Services Every 30, 60, and 90 Days, and the Minimum and Maximum Number of Days Between Services:

Bene 1:

Start Date

End Date

Jan. 1

Feb. 1

Mar. 1

Apr. 1

X

31 dys

X

28 dys

X

31 dys

X

Total of 2 Services: (Feb. 1, Mar. 1)

Bene 2:

Start Date

End Date

Jan. 1

Feb. 21

Apr. 4

Jun. 1

Aug. 15

X

51 dys

X

42 dys

X

58 dys

X

75 dys

X

Total of 3 Services: (Feb. 21, Apr. 4, June 1)

NUMBER OF SERVICES EVERY 30 DAYS:

STEP 1: Find the total number of days between the start and end dates:

Bene 1: 90 total days between the start date and end date

Bene 2: 226 total days between the start date and end date

STEP 2: Calculate the number of 30-day periods in which the beneficiary could have received a service based on the total number of days between the start and end dates:

BENE 1: $90/30 = 3$

BENE 2: $226/30 = 7.53$

STEP 3: To find the proportion of services every 30 days that the beneficiary actually did receive, divide the actual number of services by the number of services the beneficiary could have received given the total number of days between the start and end dates (from STEP 2):

BENE 1: $2/3 = .66$ services every 30 days

BENE 2: $3/7.53 = .39$ services every 30 days

APPENDIX E



CODE OF ETHICS

Having been accepted into membership in the National Association of Medical Equipment Suppliers, we do hereby subscribe without reservation to the Association's Code of Ethics.

The purpose of the Code of Ethics shall be to set and improve standards within the practice of providing home medical equipment and services. To maintain the ethical conduct and integrity of this Association, a member pledges to abide by the following:

- 1. To render the highest level of care promptly and competently taking into account the health and safety of the patient.*
- 2. To serve all patients regardless of race, creed, national origin or reason of illness.*
- 3. To provide quality home medical equipment and services which are appropriate for the patients' needs.*
- 4. To instruct the patients and/or care givers in the proper use of the equipment.*
- 5. To explain fully and accurately to patients and/or care givers patients' rights and obligations regarding the rental, sale and service of home medical equipment.*
- 6. To respect the confidential nature of the patients' records and not to disclose such information without proper authorization, except as required by law.*
- 7. To continue to expand and improve professional knowledge and skills so as to provide patients with equipment and services which are continually updated.*
- 8. To abide by both Federal and local laws and regulations which govern the home medical equipment industry.*
- 9. To avoid participating, directly or indirectly, with a source of patient referrals in a "captive referral arrangement" whereby patients are directed to utilize a supplier of home medical equipment in derogation of the patients' rights to select the suppliers of their choice.*
- 10. To act in good faith; to be honest, truthful and fair to all concerned.*

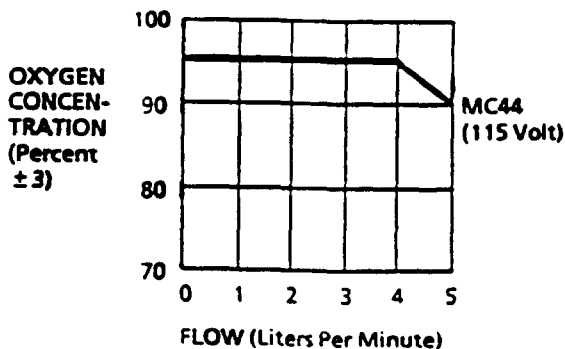
APPENDIX F

MANUFACTURER'S MAINTENANCE PROCEDURES

Every DeVO/MC44 is thoroughly tested and "burned-in" at the factory to make sure that all of the product specifications are being met. To assure continued trouble-free performance various maintenance procedures should be performed on a regular basis by a qualified DeVilbiss dealer. The following maintenance instructions are provided as a guideline.

A. Testing and Calibration

1. Turn the power switch to the "ON" position and slowly turn the flow meter control knob (6 Fig. 2) and note that the flow rate is variable from 0 to 5 liters per minute.
2. When the unit is first turned on (or if not used for an extended period of time) it may require up to 30 minutes for the oxygen concentration to stabilize. The flow rate may drift slightly during this period of time and the oxygen concentration will gradually increase to a steady value at a specific flow rate.
3. When the oxygen concentration has stabilized, an oxygen analyzer should be attached to the oxygen outlet fitting (7 Fig. 2) to test oxygen concentrations at various flow rate settings. The analyzer should be calibrated prior to taking an oxygen percentage reading (See note under 8-6). As the flow rate is increased, the percent of oxygen in the delivered gas decreases, though the actual volume of oxygen delivered per minute is greater. The range of oxygen delivered at the outlet for various flow rates is shown in the graph below for the MC44.



Oxygen Production Vs. Flow Rate

B. Routine Maintenance

1. Humidifiers - The humidifier (6 Fig. 3) should be cleaned daily or as recommended by the manufacturer. It should be washed in warm soapy water, rinsed thoroughly, and refilled. Be careful not to overfill. The tubing and prescribed cannula or mask should also be cleaned according to manufacturer's recommendations.
2. Gross Particle Filter - The gross particle filter (6 Fig. 4) should be removed and cleaned weekly.

To remove and clean:

- A. Turn the knob counterclockwise 1/4 turn and remove the entire assembly (See Fig. 5).
- B. Wash the assembly in warm soapy water and rinse. Shake excess water from the filter.
- C. Use a lint-free cloth or paper towel to dry filter. Be sure filter is completely dry before replacing.
- D. Filter may also be cleaned by vacuuming.

NOTE: The gross particle filter should be monitored more closely in environments with abnormal amounts of particulate matter in the air. Operation of the DeVO/MC44 without the gross particle filter will prematurely occlude the felt pre-filter and cause a decrease in unit performance.

3. Felt Pre-Filter - The felt pre-filter (2 Fig. 7) should be changed approximately once a month under normal conditions.

To replace the pre-filter:

- A. Rotate the filter housing (3 Fig. 7) counterclockwise to remove it from the intake bacteria filter (5 Fig. 7).
- B. Remove the cap (1 Fig. 7) on the filter housing and pull out and discard the used filter pad (2 Fig. 7).
- C. Insert a new felt pre-filter pad into the housing and replace the cap on the housing.
- D. Place the filter housing on the bacteria filter and turn clockwise until snug.

4. **Intake Bacteria Filter** - The intake bacteria filter (5 Fig. 6) should be inspected at the same time the felt pre-filter is inspected and changed when needed (approximately every six months).

To replace the intake bacteria filter:

- A. Pull the bacteria filter out of the rubber grommet (See Fig. 6).
 - B. Remove the felt pre-filter assembly
 - C. Place the felt pre-filter assembly on a new bacteria filter.
 - D. The complete filter assembly can then be inserted into the rubber grommet.
5. **Audible Alarm** - Testing the audible alarm system should be included in a routine maintenance program. It should be checked on a monthly basis.

- A. To test the audible alarm system, remove the line cord from the 115 volt AC outlet and turn the power switch to the "ON" position. If the alarm is not heard or sounds weak, replace the 9 volt battery (6 Fig. 14) located on the accumulator shelf next to the filter assembly.
- B. Plug the unit into a 115 volt AC outlet and turn the power switch to the "ON" position. The alarm will sound momentarily. If the alarm is not heard or sounds weak replace the 9 volt battery.

NOTE: Replacement batteries can be purchased locally and should be alkaline batteries or equivalent.

6. **O₂ Concentrations** - Oxygen concentrations should be checked monthly in accordance with the established test procedures (Section 4, A).

NOTE: Before checking concentrations, the oxygen analyzer should be properly calibrated using a 100% pure oxygen source. It should also be noted that changes in temperature, altitude, or humidity may affect the oxygen concentration reading as shown by the analyzer. Therefore, the analyzer should be calibrated in similar conditions to where the concentrator is located.

C. Periodic Maintenance

1. **Final Bacteria Filter** - The final bacteria filter (3 Fig. 12) should be changed as needed (approximately once a year under normal conditions).

To replace the final bacteria filter:

- A. Loosen the cabinet fasteners on the top and sides of the unit.
 - B. Swing the front cover to the right.
 - C. Remove hose clamp and hose from each end of filter and discard filter.
 - D. Install new bacteria filter and secure with hose clamps.
 - E. Replace cover and secure with cabinet fasteners.
2. **Compressor Filter** - The compressor HEPA filter (13 Fig. 14) should be changed at or before 25,000 hours of unit operation.

To replace compressor filter:

- A. Refer to Service Instruction 8 to open cabinet covers. The back cover should be completely removed.
- B. Cut plastic cable tie that holds HEPA filter in place.
- C. Loosen hose clamps and remove black rubber hose from both ends of filter.
- D. Install new HEPA filter with air flow directional arrow pointing downward and secure with plastic cable tie.

NOTE: Holes for cable tie are located directly behind left sieve bed. Thumb screws and brackets that secure beds to unit must be removed so that cable tie can be inserted into holes.

- E. Attach black rubber hoses to each end of filter and secure with hose clamps.
 - F. Replace cabinet covers and secure with cabinet fasteners.
3. **Compressor** - Inspect and change if necessary the internal components at 10,000 hour intervals of unit operation. See Service Instruction 1.

NOTE: All routine and periodic maintenance should be recorded by listing the date and hour readings in a maintenance schedule like the one shown on the following page.

MODEL

SERIAL NO.

SET UP DATE

The user to perform only the following:

- Clean cannula/mask and humidifier daily.
- Clean gross particle filter weekly.

| RECOMMENDED SERVICE INTERVALS | | MONTHLY LOG | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|--|-------------|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 |
| Date of Service | Record at Each Maintenance Check | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hours on Meter | Record at Each Maintenance Check | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Concentration | Check Monthly | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 9 Volt Battery | Change as Needed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Felt Pre-Filter | Change Once Per Month or as Needed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Intake Bacteria Filter | Change as Needed (Approx. Every 6 Mos.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Final Bacteria Filter | Change as Needed (Approx. Once a Year) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Compressor | Inspect Internal Components at 10,000 Hrs. of Unit Operation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Compressor HEPA Filter | Change at or Before 25,000 Hrs. of Unit Operation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

DeVO/MC44 Maintenance Schedule

APPENDIX G

TYPICAL VA CONTRACT Oxygen Concentrator Requirements

Contractor to furnish all labor and equipment required to provide rental service of oxygen concentrators for VA beneficiaries in their homes within geographical jurisdiction of the VA Medical Center (city, state).

Contractor will be responsible for providing the VA beneficiary with all disposables such as nasal cannulas or masks, tubing, connectors, nebulizers, humidifiers and bottles (Aquapak, or equal substitute). Also, the contractor will be required to furnish emergency back-up systems: "E" size cylinder or "H" size cylinder as appropriate, cart, flowmeter/regulator, wrench, etc. and will also provide the vendor service for the refills of these cylinders.

MONTHLY RENTAL COST FOR HOME USE WILL INCLUDE THE FOLLOWING:

- o O2 concentrator and necessary disposable equipment, i.e., nasal cannulas or mask, humidifiers, nebulizers, extension tubing, etc. Replacement of disposables PRN.
- o Initial set-up and education of patient by qualified respiratory therapist.
- o All equipment and supplies necessary for back-up O2 to cover response time in case of equipment or power failure.
- o Monthly equipment maintenance and inspection visits.
- o Monthly monitoring visits by a registered or certified respiratory care practitioner to evaluate all aspects of the services being provided to the patient.
- o Equipment must be cleaned and serviced on a regular basis.
- o Delivery within the VA facility's jurisdiction service area to include the counties shown on Page ____.
- o Contractor will provide service 7 days a week, 24 hours a day.
- o Concentrators furnished under this rental agreement shall be covered by U.L. Listed Reference No. E71727, grounding required, be double insulated with an operating pressure of 25 psi - compressor thermally protected. The concentration shall be 93% to 100% plus or minus 3%, oxygen at all flows and flowrate shall be

sufficient to provide 1, 1.5, 2, 3, or 4 liters/minute. Unit shall be equipped with an audible alarm and warning lights for signalling concentrator failure. The unit shall be sufficient to require only minimum service by VA beneficiary; i.e., twice weekly external filter cleaning, etc.

- o Rental price indicated shall include VA beneficiary and family training, observation in use, follow-up service on rental unit every 6 to 8 weeks and 24-hour emergency service coverage 7 days a week. Contractor to provide each VA beneficiary with the telephone number for obtaining such service.
- o All units currently in use as stated in the requirements must be installed and operating in the VA beneficiary's home within forty-five (45) calendar days after award of contract. The successful bidder will be required to coordinate exchange with the present contractor for the transition (in the event the present contractor is not the successful bidder).
- o Contractor will be responsible for providing patient with all disposables and back-up systems as appropriate. Copy of all documentation of service calls and routine and emergency visits to the VA beneficiary's home, and visit assessments will be sent to Chief, Prosthetic Service.
- o Because of the age, condition, etc., of the VA beneficiary for whom the service is being provided, it is recommended, particularly in cases where a unit is being exchanged due to equipment failure, that the exchange be accomplished with a unit of the same type to avoid unnecessary confusion.
- o SPECIAL NOTE: Descriptive literature must be furnished with offer on the unit he/she proposes to furnish under this contract. Please indicate below nomenclature of this proposed unit (Brand, Model#)_____.

APPENDIX H

Comments from the Health Care Financing Administration

Comments from the National Association for Medical Equipment Services

Comments from the Health Industry Distributors Association

Comments from the Health Industry Manufacturers Association

Comments from the American Association for Respiratory Care



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date OCT 20 1994
From Bruce C. Vladeck *Bruce Vladeck*
Administrator
Subject Office of Inspector General (OIG) Draft Report: "Oxygen Concentrator Services"
(OEI-03-91-01710)
To June Gibbs Brown
Inspector General

We reviewed the above-referenced report which found that some Medicare beneficiaries who use home oxygen concentrator therapy receive extensive services while others receive few.

We agree with the report's recommendation that educating providers and beneficiaries about standards for necessary and standard care is important. However, we believe that options 2 and 3 may not be feasible because of the inherent administrative burdens.

Our detailed comments on the report's findings and recommendation are attached for your consideration. Thank you for the opportunity to review and comment on this draft report. Please contact us if you would like to discuss our comments and response.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on Office of Inspector General (OIG) Draft Report:
"Oxygen Concentrator Services"
OEI-03-91-01710

Recommendation

HCFA should produce a strategy to ensure that Medicare beneficiaries receive necessary care and support in connection with their oxygen therapy.

HCFA Response

We agree that suppliers should provide necessary services in connection with the oxygen equipment and supplies they furnish, and that HCFA should be doing more to ensure that Medicare beneficiaries receive the appropriate level and quality of oxygen services that they require.

Rather than promoting new standards and accreditation, however, we believe that the existing supplier standards could be used to improve service to beneficiaries. For example, if supplier practices today are the same as those reported in 1991, it would appear that the suppliers are violating the recently implemented Medicare supplier standards.

- A supplier that does not follow the maintenance procedures of the equipment's manufacturer would be in violation of standard five: "A supplier maintains and repairs . . . items it has rented to beneficiaries."
- In addition, standard four, "Answering any questions or complaints from beneficiaries," standard two, "Requiring suppliers to be responsible for delivery of items," and standard seven, "Requiring disclosure of consumer information to beneficiaries," require overall education of the patient and family regarding the use of the equipment.

HCFA will continue to encourage the durable medical equipment (DME) regional carriers to review suppliers for compliance with Medicare requirements and standards. The DME regional carriers are required to follow up on beneficiary complaints that they or the National Supplier Clearinghouse (NSC) receive. In addition, one of the conditions for obtaining a supplier number requires each applicant to note any license, certification, or accreditation required by the State where the supplier does business. The NSC is building a data base of State requirements and will randomly select applicants for verification.

Page 2

We will also pursue providing further specifications in manual instructions to state exactly what is required under the current supplier standards for oxygen services. For the other patient monitoring services described in the report that are not encompassed in the current standards, HCFA will consider whether it would be appropriate to require suppliers to provide such services.

Finally, we agree with the recommendation to educate providers and beneficiaries, and will include Medicare supplier standards information in our beneficiary and provider education strategies.

Option 1

HCFA could initiate a program to educate providers and beneficiaries about the kinds of services available and recommended by national organizations for patients receiving oxygen therapy. Such an educational initiative might be most effective if undertaken in partnership with relevant professional associations.

HCFA Response

We concur with the recommendation of an initiative to educate providers and beneficiaries which will enable Medicare beneficiaries to make informed decisions about their health care needs and help health care professionals provide or arrange for the best possible medical care for beneficiaries. The DME regional carriers can use carrier newsletters to advise health professionals and providers about the importance of servicing oxygen equipment and meeting the supplier standards. Additionally, beneficiaries should be encouraged, by their provider, to select suppliers who are in the "Participating Supplier Directory."

We further believe that physicians who order oxygen for beneficiaries have a responsibility to advise them on the use and basic maintenance of the equipment. We do not believe that use of the Medicare Handbook to educate beneficiaries about the specific services suppliers should offer would be cost-effective because less than 1 percent of beneficiaries use oxygen. However, we will consider sending out a special mailing to Medicare beneficiaries, or drafting a notice for providers to send to their Medicare patients who need oxygen therapy services, listing the standards or service requirements for Medicare suppliers.

Page 3

Option 2

HCFA could promote standards for oxygen therapy services which suppliers should provide to Medicare beneficiaries.

HCFA Response

We agree with the intent of the recommendation. However, as stated above, rather than promoting new standards for accreditation, we believe that the existing supplier standards should be used to improve oxygen services provided to beneficiaries.

In addition, we believe that providing financial incentives to some suppliers could result in a heavy administrative burden for the Medicare program. (Please note that making differential payments to oxygen suppliers that are accredited would require a legislative change.)

Option 3

HCFA could establish a minimum level of service requirements for suppliers.

HCFA Response

We do not concur. Setting minimum requirements for purposes of accreditation, certification, or licensure is a process generally reserved for entities that furnish direct patient care and not for suppliers of medical equipment. Again, as stated before, we believe that the existing supplier standards should be used to improve oxygen services provided to beneficiaries.



NAMES

National Association for
Medical Equipment Services

September 30, 1994

HAND DELIVERY

The Honorable June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Cohen Building
Room 5250
Washington, D.C. 20201

Re: Comments on Draft Report
Oxygen Concentrator Services
OEI-03-91-01710

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|-----------|------------|
| IG | _____ |
| SAIG | _____ |
| PDIG | _____ |
| DIG-AS | _____ |
| DIG-EI | _____/____ |
| DIG-OI | _____ |
| AIG-CFAA | _____ |
| AIG-MP | _____ |
| OGC/IG | _____/____ |
| EXSEC | _____/____ |
| DATE SENT | 9/30 |

Dear Ms. Brown:

The National Association for Medical Equipment Services ("NAMES") appreciates very much the opportunity to provide comments on the draft Department of Health and Human Services, Office of Inspector General ("OIG"), inspection report entitled, "Oxygen Concentrator Services." The report discusses the nature and extent of services provided to Medicare beneficiaries who use oxygen concentrators.

I. General Comments

NAMES concurs with the OIG's conclusion that the use of oxygen concentrators in the home requires a high level of service for oxygen-dependent individuals, and it endorses the OIG's recommendations for increased education and industry standards to enhance the level of services. As the draft report recognizes, NAMES has been active in promoting service standards to its members for many years. NAMES, therefore, supports the OIG's recommendation to the Health Care Financing Administration ("HCFA") to consider various strategies, including supplier and beneficiary education and establishing minimum supplier service standards for the provision of oxygen concentrator services to Medicare beneficiaries.

As set forth below, however, NAMES believes that some of the language of the draft report, and the underlying data used by

David J. [unclear]

the OIG to develop its findings, misrepresent the current state of oxygen supplier services and care for oxygen patients. In particular, the draft report fails to provide a complete picture of the scope and nature of accreditation within the home medical equipment ("HME") industry by the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"). While the draft report acknowledges that its findings are based upon 1991 data, and that "concerned organizations have implemented improved standards of care since then" (Report, p. 15), NAMES strongly believes that further caveats are necessary to provide a complete and accurate picture of the industry. During 1991, JCAHO accreditation -- which mandates specific equipment service requirements -- was still in its infancy. Few suppliers had been accredited, simply because of the newness of the process, the considerable cost, and JCAHO's preliminary delays in scheduling surveys of those suppliers which had sought accreditation.

Today, 1,420 suppliers have been JCAHO accredited. Many of these accreditations have taken place during the last three to four years -- subsequent to the time of the study. Moreover, the industry has seen some degree of consolidation during that time period, increasing overall the percentage of accredited suppliers. NAMES, of course, is understandably concerned with findings of the draft report that some of the Medicare beneficiaries surveyed received no patient care or equipment monitoring services whatsoever. Nonetheless, NAMES believes it is critical to place these findings in the proper historical context. NAMES urges that the report specifically identify JCAHO accreditation as a relatively new option for suppliers, and also note that the 1991 data sample occurred prior to the accreditation movement within the industry being fully underway.

II. Specific Comments on the Draft Report

Specific comments on the draft report by page number are detailed below:

Executive Summary, p. i, Report, p. 1.

The draft report states that patients using items such as wheelchairs and hospital beds "require little monitoring." NAMES believes this sentence to be both unnecessary and inadvisable. For example, severely disabled patients (especially children) utilizing custom wheelchairs, and ventilator-dependent patients and others whose health is severely compromised, require substantial patient and equipment monitoring. NAMES certainly

concur that oxygen therapy patients require attention, but would avoid making sweeping comparisons which may be of limited applicability.

Executive Summary, p. ii

NAMES recognizes that an Executive Summary is designed to provide a snapshot of a larger document. At the same time, NAMES is concerned that the specific findings which the OIG has chosen to include in the Executive Summary paint the HME services industry in the worst light possible. NAMES has worked very hard to improve the image of the industry as a whole, and while there is no desire to state the results of the study inaccurately, NAMES is concerned that findings of the Executive Summary taken out of context will undermine NAMES' efforts to improve the industry image as a whole. For example, the draft report states on p. ii (and on page 10 of the report in substantially similar language) that "Nearly half of all beneficiaries -- 47 percent -- do not receive any patient care evaluations or assessments from suppliers." Stated another way, over half of all beneficiaries do receive such services. Similarly, one other pertinent finding from the report should be included in the Executive Summary:

Ninety-two percent of Medicare beneficiaries received one or more equipment services and, of these, 71.5 percent of patients received services every 60 days, in accordance with NAMES' standard, which advocates one equipment service every 60 days.

Executive Summary, Page ii

NAMES does not believe it correct to state that the Department of Veterans Affairs ("VA") has "endorsed" a set of "recommended services." As discussed below, there are significant limitations with trying to compare services provided to veterans under VA contracts and those provided to Medicare beneficiaries, in part because there is no uniform standard of required services under VA contracts, nor any review to assess what services are actually performed.

Report, p. 2

The section entitled "Changes in Claims Processing Environment" incorrectly states that these changes were based on the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90"). In

fact, these changes were implemented as a result of an independent HCFA initiative permitted by provisions of OBRA '87 and subsequently codified into statutory language.

More importantly, the report alleges that there have been concerns about abusive practices by HME suppliers "since Medicare's inception." The report enumerates carrier shopping, multiple supplier billing numbers, telemarketing, and the like. NAMES believes this introductory provision to be unduly negative and irrelevant to the report itself. There is no need to include this background in a discrete study of services provided for one type of equipment. Again, NAMES is very concerned that gratuitous comments like this will undermine NAMES' efforts to improve the quality of its members, and will serve to frustrate even further legitimate, ethical suppliers who maintain honest business practices.

Report, p. 3

Previous Office of Inspector General (OIG) Work

NAMES is concerned about the appropriateness of including findings from past OIG studies on home oxygen and oxygen equipment in this report. As discussed below, given the serious methodological problems with several of these studies, and the negative and gratuitous comments about their conclusions, NAMES recommends that this section be deleted, particularly because it does not provide any insight into the objectives, findings or recommendations of this report.

The OIG references two studies conducted in 1987 and 1991, respectively, in which the OIG attempted to compare oxygen concentrator payment levels by Medicare and the VA. As NAMES has commented previously, this is an "apples to oranges" comparison, because Medicare oxygen concentrator payments are not structured the same way as VA payments. For example, most VA contracts have separate payments for portable oxygen contents, while the Medicare payment includes portable contents. Even the OIG's own study indicated that VA disbursements for oxygen contents may not be retrievable, thus preventing a meaningful comparison to the Medicare stationary fee which includes portable contents. Further, while VA contracts typically enumerate certain service requirements, the VA has no post-contract review, audit, or similar survey process to determine whether these services are actually provided. Thus, cost breakdowns -- comparing what is actually provided by a Medicare supplier in a sample study with

what a VA contractor is required to provide -- are not necessarily reliable. Finally, Medicare suppliers are required to incur considerably more administrative costs, such as monthly claims submission, obtaining from physicians properly completed certificates of medical necessity, and the like. Thus, NAMES believes there are serious limitations to the usefulness of such a comparison, and the reference to these studies in this report.

The OIG also references a 1990 study entitled "National Review of the Medical Necessity for Oxygen Concentrators," which reported that one-third of the sampled beneficiaries in the study "did not need oxygen or did not need oxygen to the extent billed." NAMES questions how the OIG could have concluded that these patients did not need oxygen, since medical necessity for oxygen therapy is determined by objective standards for partial pressure of oxygen (PO_2) in arterial blood or oxygen saturation levels by ear or pulse oximetry. These had to have been documented in order for Medicare payment to be made. NAMES also questions the 1990 report's language with regard to patients not needing oxygen "to the extent billed," since there is only one flat monthly fee that may be billed to the Medicare program.

Methodology

In the section entitled "Methodology," the report discusses the sample used to conduct this study. As discussed above, data drawn from 1991 is not representative of the industry today. Accredited organizations represent an ever increasing share of the HME industry. Further, it is unclear whether 183 suppliers selected for this study represent distinct corporate entities, or whether individual branches of the same company are counted as separate suppliers. This is significant because, to the extent this represents individual corporate entities (rather than branches of the same organization), the data would be skewed to representing smaller suppliers which may, in the past, not have had the resources to seek JCAHO accreditation or to provide enhanced levels of service. Accordingly, the size and resources available to the suppliers in the study needs to be clarified. Also, we understand that one of the suppliers in the sample was sold during the period in question. As a result, the OIG was evaluating old paperwork, while patients were actually being served by a new supplier under new protocols. Thus, beneficiaries may have actually been receiving considerably more services than were documented by the predecessor supplier. Finally, we question whether a 0.1 percent beneficiary sample size is statistically significant. At the initial meetings on this study, the OIG

assured NAMES that the groups chosen were statistically valid. That proof should be appended to the final report.

Report, p. 4

Paragraph four on this page indicates that disposable equipment drop-offs were not included in the classification of equipment and patient monitoring services. It is likely that equipment monitoring or clinical visits were made in conjunction with some disposable drop-offs, particularly where registered therapists made these deliveries, even if these services were not properly documented. This is because most suppliers attempt to coordinate such deliveries with other services as a means of achieving higher cost efficiency. Without JCAHO accreditation, suppliers may have been less likely to record the services performed in a service file or comparable patient record. Thus, the exclusion of these services (due to lack of documentation) may have unduly skewed the results towards a finding of a lower amount of supplier services.

Report, p. 5

In paragraph four, the report does not indicate whether the documentation requested and credentials of supplier staff were found to be valid. In paragraph six, the full names of NAMES is written incorrectly. The correct name of the association is the National Association for Medical Equipment Services.

Report, p. 6

The third full paragraph on this page discusses JCAHO, but fails to include the details noted above. Further, not only has the number of suppliers who are accredited increased substantially since 1991, but the number of beneficiaries receiving services from accredited suppliers has increased as well. This is due in part to the increased number of accredited suppliers, as well as other forces resulting in patients obtaining services from accredited suppliers, such as consolidation within the industry, competition and the increased emphasis on standards by industry associations.

Report, p. 7

In the section entitled "Payers mandate service requirements for beneficiaries," the OIG discusses contracts which the VA and state Medicaid agencies enter with suppliers, and goes

on to use provisions of some of those contracts as "standards" which have been "endorsed." NAMES does not believe this to be an accurate characterization. Moreover, as discussed above, NAMES urges that the report point out an inherent limitation in its analysis: namely, that no survey was undertaken to determine whether the requirements set forth in these contracts in fact were being carried out, or whether these requirements achieve efficiency and cost-effectiveness. NAMES members provided OIG representatives with numerous specific examples of instances in which entities which were awarded VA contracts in fact provided no services whatsoever, or provided only some services or different services. NAMES believes that this type of "anecdotal information" with respect to limitations in the report's methodology should be included to the extent that the draft report itself includes "anecdotal information" with respect to individual suppliers (see page 13).

Report, p. 8

Table 1 purports to project the findings of the study to all beneficiaries nationwide. Once again, as the sample does not accurately represent the characteristics of the overall HME supplier industry, it is not appropriate to project the findings across the national pool of beneficiaries. This table, as well as Tables 3 and 5, should therefore be eliminated (or at a minimum, only show the percentages and not the national beneficiary estimates).

Report, pp. 9-12

As discussed above, the findings as displayed in Graph 1, Table 2, Graph 2, and Table 4 may be significantly skewed by the types of suppliers in the study and the data irregularities cited earlier. The level of services provided by suppliers in the 1991 sample cannot necessarily be extrapolated to a "typical" Medicare beneficiary.

Report, p. 13

The draft report includes several anecdotal comments about suppliers who did not provide services, but includes no comparable descriptions of the many suppliers who have gone out of their way -- for example, during Hurricane Andrew and the devastating floods in the Midwest and Georgia -- to service their patients. NAMES urges that "equal time" be given to a description

The Honorable June Gibbs Brown
September 30, 1994
Page 8

of suppliers providing patient and equipment monitoring services, as well as those who did not.

Report, p. 14

The draft report states that "[s]uppliers providing necessary services. . . are placed at a competitive disadvantage." NAMES questions this statement. At least in some markets, competitive forces will drive (and have clearly driven) some suppliers not providing the necessary services out of business. The respiratory care industry is driven by service.

The report goes on to explain that HCFA has no recourse against a company providing minimal or sporadic services because it has not adopted service standards against which to measure supplier practices. This is essentially correct. While HCFA has adopted minimal standards relating to more generic requirements for HME (e.g., responsibility for delivery of items to Medicare beneficiaries, honoring warranties, maintaining and repairing equipment, and the like) (42 C.F.R. § 424.57(c)), and HCFA may revoke a supplier's Medicare supplier number for failing to adhere to these standards, HCFA, regrettably, has not yet adopted, nor endorsed accrediting bodies' or other organizations' standards, for equipment and patient monitoring. As discussed below, NAMES endorses the recommendations made by the OIG in the final section of the report to encourage higher levels of service.

Report, p. 15

At the top of the page, the draft states:

We recognize that our data represents the state of care provided by suppliers to Medicare beneficiaries in 1991, and concerned organizations have implemented improved standards of care since then. (Emphasis added.)

NAMES believes it appropriate to note specifically that numerous HME suppliers in fact have been accredited since that time.

Report, p. 15

The draft report provides several recommendations under the rubric of "Educating Providing and Beneficiaries." NAMES

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Page 9

urges that the report note that NAMES in fact has already undertaken some of these efforts, i.e., "informing beneficiaries of the kinds of services they should look for from their suppliers." NAMES of course would be happy to work with the OIG and HCFA to undertake further efforts, including, for example, a section in HCFA's Medicare Handbook.

Report, p. 16

NAMES has been a longstanding advocate of promoting standards for the provision of HME services, including the requirement for supplies "to render the highest level of care promptly and competently taking into account the health and safety of the patient." See Attachment E to the draft report. NAMES is committed to working with the OIG and HCFA for development and adoption of such standards.

The OIG has recommended three different approaches for setting minimum requirements: (1) accreditation by a nationally recognized organization, such as JCAHO or the Community Health Accreditation Program ("CHAP"); (2) certification by suppliers meeting accreditation requirements if, for financial or other reasons, the supplier has not undergone an inspection process to become officially accredited; or (3) state licensure.

Because most states do not license HME suppliers, NAMES does not believe this approach alone is an effective means to ensure minimum requirements. Additionally, because many suppliers do not have the resources to become accredited by JCAHO or CHAP, NAMES endorses the option of allowing suppliers either to become accredited or to certify annually to their Durable Medical Equipment Regional Carriers ("DMERCs") that they meet one or more of the proposed alternatives.

NAMES believes the preferred approach is for HCFA, in consultation with NAMES, to develop specific supplier standards for the provision of equipment monitoring and patient care services to add to the existing supplier standards. These standards should encourage high quality beneficiary outcomes, as well as efficiency and cost-effectiveness, in today's marketplace. Such standards should be reviewed periodically to ensure that they reflect current techniques and technological developments. Suppliers found to be out of compliance with these requirements would then be subject to having their supplier number revoked or other appropriate corrective action.

The Honorable June Gibbs Brown
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Page 10

Whatever option is adopted, NAMES strongly urges that consideration be given to the recommendation of the Business Roundtable's newly published "white paper" Toward Smarter Regulation that "paperwork burdens caused by regulatory programs should be expressly assessed and substantially reduced." While NAMES shares the OIG's concerns that Medicare beneficiaries -- indeed, all patients -- receive regular, high quality services, it urges caution in mandating any extensive new paperwork requirements.

III. Conclusion

NAMES supports the OIG's conclusion that the provision of home oxygen concentrator services requires an intensive service component, and appreciates the OIG's consideration of this important issue. At the same time, NAMES questions some of the findings in this study, based on the age of the data and the supplier sample. NAMES believes the industry has moved consistently and aggressively to becoming more service oriented, as evidenced in the December 1993 Report entitled "NAMES Consensus Conference on Home Medical Equipment Services." This is reflected by the increasing number of suppliers who have obtained JCAHO and CHAP accreditation. NAMES requests that the draft report be revised to reflect the comments provided herein, including in particular avoiding references to the negative image of the HME industry which NAMES has fought so hard to dispel.

Should you or your staff have any questions on these comments, we would be happy to discuss them with you at your earliest convenience.

Respectfully submitted,

A handwritten signature in cursive script that reads "Corrine Parver".

Corrine Parver
President



HEALTH INDUSTRY
DISTRIBUTORS
ASSOCIATION

225 Reinekers Lane, Suite 650
Alexandria, VA 22314-2875 703-549-4432 FAX 703-549-6495

BY HAND DELIVERY

September 30, 1994

June Gibbs Brown, Inspector General
200 Independence Avenue, SW
Department of Health and Human Services
Washington, DC 20201

Dear Inspector Brown:

| | |
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| DATE SENT | 9/30 |

This letter contains our comments on the Office of Inspector General's draft report on Oxygen Concentrator Services (July 1994, OEI-03-91-01710). Thank you for the opportunity to comment, and we look forward to our continued dialogue on this report and other issues that impact HIDA members.

I. Introduction

HIDA is the national trade association of health and medical product distribution firms. Created in 1902 by a group of medical products business people, HIDA now represents more than 1000 wholesale and retail distributors with approximately 2000 locations. HIDA members include a broad range of health and medical product distributors — billion dollar multi-location national companies and neighborhood stores, chains, and independents. HIDA members provide value-added distribution services to virtually every hospital, physician's office, nursing home, clinic, and other health care site in the country, and to a growing number of home care patients. We are writing on behalf of our members who provide Medicare Part B home oxygen services to Medicare beneficiaries pursuant to a physician prescription.

II. General Comments

HIDA applauds the IG's efforts to study the level of services suppliers currently provide to Medicare beneficiaries receiving home oxygen therapy. We agree with the IG's findings that there is a tremendous amount of inconsistency among suppliers in terms of the level of services they provide to their home oxygen customers. We therefore strongly support the IG's recommendation to establish supplier standards. We believe that defining standards of service will result in suppliers providing the highest level of service and care to Medicare beneficiaries. We also strongly support extending the standards to non-participating suppliers in addition to those who take Medicare assignment. The National Supplier Clearinghouse, which receives information about all suppliers' services through the Form HCFA-192, is an ideal mechanism for establishing service level requirements for suppliers. Attached are Consensus Conference recommendations we developed in 1992 to achieve this objective.

While we are very pleased at the progressive nature of the IG's recommendation to establish separate payment amounts based on service levels, we are unable to fully commit HIDA

Reid ES
9/30/94

support to this recommendation until further policy analysis, and importantly, the administration (e.g. DMERC) implications are explored. The policy analysis needs to consider patient outcomes-driven levels of service rather than only supplier company capability. While traditionally competitive market forces have caused high service levels balanced by regulatory driven fee schedules, the emerging integrated managed care markets are changing these incentives and restraints. Thus, any linking of reimbursement to service levels needs to consider the emerging operating environment for home health delivery.

III. Specific Comments

Although we are generally pleased with the IG's findings and recommendations, we have several specific comments which we believe would improve the report.

On page 4, the last paragraph's third sentence states that the IG consulted with a "registered nurse with an extensive background in pulmonary care" for assistance with the report's analyses. We question whether your registered nurse with a background in pulmonary care has the necessary qualifications or experience in home care to evaluate home oxygen services. We believe it would have been more appropriate to have consulted with a health care professional with specific home care expertise for a more accurate evaluation. The operating experience in an institutional setting is not the same as experience in the home and is therefore not intuitively transferable.

On page 5, the sixth paragraph, we question why the organizations the IG met with are not listed alphabetically. We also request that HIDA's acronym -- HIDA -- please be added after the spelling out of the Health Industry Distributors Association as is done with other organizations mentioned in the list.

On page 6, the third paragraph describes the national accrediting bodies which establish service standards for home oxygen care. The last two sentences in the paragraph describe the number of suppliers who have maintained JCAHO accreditation and the number planning to seek accreditation in the future. We believe more useful information would be the number of beneficiaries who were served by those suppliers who maintained accreditation.

On page 7, the report neglects to mention HIDA's recommendations to the IG about supplier service standards. HIDA has recommended different levels of standards depending upon the type of services the supplier provides, such as basic standards for traditional DME, higher standards for oxygen (e.g., respiratory care), and even more stringent standards for higher care patients on ventilators or those receiving home infusion therapy. HIDA continues to fully support these standards and would appreciate mention as such in the report.

On page 12, the report describes the number of beneficiaries whose supplier failed to meet service standards set by the VA and AARC. The section should also evaluate which suppliers which are JCAHO accredited failed to meet JCAHO service standards.

On page 16, "Promoting Standards," the report recommends HCFA promoting standards endorsed by several organizations, including NAMES. To identify standards, we believe a consensus process such as JCAHO is preferable to a narrower industry development such as NAMES.

On page 16, "Setting Minimum Requirements," the report describes several mechanisms to establish a minimum level of service requirements for suppliers. HIDA recommends that the IG consider the National Supplier Clearinghouse (NSC) as a mechanism through which to establish service level requirements for suppliers. All suppliers must complete a Form HCFA-192 and submit it to the NSC. The form could include questions about services provided to establish service level requirements for that supplier. Please see our attached 1991 Consensus Conference recommendations for more details on supplier requirements.

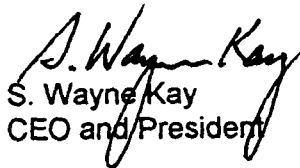
IV. Conclusion

HIDA supports many of the findings and recommendations in this report. Unlike other items of durable medical equipment, home oxygen therapy is life-sustaining and therefore requires regular equipment and patient monitoring services. Unfortunately, current Medicare policies have not recognized that services should be provided, which has resulted in variation among service levels for beneficiaries.

Home care dealers would benefit from supplier service standards for oxygen therapy. Patients who depend on home oxygen therapy to function would benefit from a more consistent level of service rather than their random selection of a supplier. HIDA supports having Medicare educate providers and beneficiaries about the kinds of services which should be provided to home oxygen patients. HIDA supports promoting industry service standards and recommends that the NSC be used as a mechanism for evaluating which suppliers (depending on their level of care patients) should be required to meet which standards. Finally, HIDA supports requiring suppliers to meet accreditation, certification or licensing requirements.

Thank you for the opportunity to comment. Please contact me or Cara Bachenheimer, HIDA's director of government relations, for further information.

Sincerely,


S. Wayne Kay
CEO and President

Attachment

cc: Penny Thompson, OIG
HCMG, HCGRTF
Cara Bachenheimer
Craig Jeffries

ccb/ig/o2rptmt

EXECUTIVE SUMMARY

1991 HIDA Claim Efficiency
Consensus Conference
(May 13-14, 1991)

OVERVIEW

As the nation, and Congressional and Administration leaders focus on the costs of the health care delivery system, and particularly the growth of Medicare expenditures, it is important to look for areas of inefficiency. One particularly inefficient area is the administration of third party claims by Medicare carriers, home medical equipment service and long term care suppliers, and beneficiaries.

The 1989 HIDA Home Care Financial Survey reported that home medical equipment (HME) industry resources were increasingly being diverted from patient care services to the administration of third party claims. Moreover, the high cost of administering third party claims could not be reduced without the active and focused attention and support of the Health Care Financing Administration (HCFA). Therefore the 1990 HIDA Claim Efficiency Consensus Conference identified key areas for improvement.

The 1991 Conference recognized the important strides Congress and HCFA made to address the 1990 recommendations, addressed further implementation issues for old issues, and identified certain new issues. Importantly, legislation introduced in the 102nd Congress will further the implementation of many of the 1991 HIDA Claim Efficiency Consensus Conference recommendations.

PURPOSE

HIDA initiated the Claim Efficiency Consensus Conference to identify problem areas in claim processing and to recommend specific changes that will allow HME and long term care suppliers to operate more efficiently and reduce their costs of third party administration. The Consensus Conference recommendations also recognize benefits to HCFA and Medicare carriers through greater system standardization, accountability and enhanced communication.

Finally and most important, the Consensus Conference recommendations highlight emerging risks to Medicare beneficiaries of not receiving needed HME services due to barriers or inconsistent interpretations created by the problems in third party administration.

The 1991 HIDA Claim Efficiency Consensus Conference recommendations are attached and reflect the discussion of the conference participants, recorded and drafted by workgroup leaders. The recommendations have been reviewed by a broad sweep of the HME services and long term care supply industry, including participants in the 1991 conference, state association leaders and other industry representatives, and HCFA and General Accounting Office officials. Final policy recommendations emerged from this review and consensus process, and suggest cooperative action involving Medicare carriers, HCFA, and industry. Some recommendations may be implemented administratively. In some cases recommendations may require Congressional consideration and legislative action.

MAJOR RECOMMENDATIONS:

Supplier Number Qualification and Review

The HIDA Claim Efficiency Consensus Conference recommends that Medicare require suppliers (through an application process) to meet national standard criteria for issuance of supplier numbers, and periodically renew the supplier number. The standard criteria are intended to establish basic business standards that suppliers must meet (e.g., maintain inventory; FDA, OSHA, DOT compliance) and provide information suppliers would disclose to allow the carrier to monitor the supplier for potential abusive activity (e.g. telemarketing; physician self-referral). The renewal process would allow HCFA, carriers and the Inspector General to more actively monitor changes in business practices.

Beneficiary Verification System

The HIDA Claim Efficiency Consensus Conference recommends a point of service system to allow a beneficiary to verify his or her eligibility for Medicare services. This verification would include non-medical necessity elements, e.g., Part B eligibility, HIC number, address, MSP types. Such a system would be available to qualified suppliers and would be similar to the verification system currently in use by hospitals under Part A.

EMC Standardization Implementation

HCFA developed a standardized electronic media claim (EMC) format in part based on the 1990 HIDA Claim Efficiency Consensus Conference recommendations. The 1991 Conference recommendations address implementation issues to support HCFA, carrier and supplier goals in achieving an EMC capability, including systems standardization, adequate carrier support systems, crossover claims processing, query capability, standardization of EOMB messages, code and medical policies. The recommendations also address problems of access to EMC by small volume suppliers.

National Standard Coverage and Utilization

The HIDA Claim Efficiency Consensus Conference recommends the establishment of national standard Medicare coverage criteria and utilization guidelines to curb abusive carrier shopping.

Carrier Consolidation

The HIDA Claim Efficiency Consensus Conference reconfirms the 1990 recommendation to consolidate the number of carriers to achieve better carrier management and carrier claim processing expertise on HME and long term care supply claims.

Carrier Jurisdiction Rules

The HIDA Claim Efficiency Consensus Conference recommends that claims must be submitted to the carrier with jurisdiction where the patient resides except that HCFA may allow carriers to exempt suppliers that service patients residing within 60 miles of the carrier area, "snowbird" beneficiaries, and for other reasons with no potential for abuse.

HIDA Home Care
225 Reinekers Lane, Suite 650
Alex., VA 22314
(703) 549-4432

HIDA Claim Efficiency Consensus Conference
Conference Leaders: Craig Jeffries, HIDA
Cullen Murphy, Wasserotts
Cara Bachenheimer, HIDA
May 13-14, 1991

Workgroup Topics

I Insurance Verification

Leaders: Lisa Thomas-Payne, Medical Reimbursement Systems; Joanna Augst-Johnson, Redline.

Participants: Stephanie Thornton, ADMEA; Dawn Wright, Stein Medical; Tina Morrelli, HCFA; Melanie Combs, HCFA.

II Carrier Performance; Medicare Carrier Reform: Regional Carriers; Clean Claim Reforms, TAG.

Leaders: Lynn Snyder, Epstein, Becker & Green; Tim Redmon, NARD

Participants: Al Schnupp, GAO; Ann Berriman, Ober, Kaler & Grimes; Susan Kladiva, GAO; Geraldine Wnuk, Buffalo Hospital Supply.

III EMC/Paper Processing

Leaders: Maureen Hanna, Abbey Home Healthcare; Cynthia Bentley, Homedco

Participants: Max Buffington, HCFA; Jim Kral, HCFA; Carolyn Harris, Glasrock; Gordon Hilton, Abbey Home Healthcare.

IV Supplier Number and Carrier Shopping

Leaders: Rita Hill, American Home Patient Centers; Dan Moskowitz, ASCO.

Participants: Jane Herlocker, HCFA; Mike DeCarlo, NAMES; Cara Bachenheimer, HIDA.

HIDA CONSENSUS CONFERENCE
May 13-14, 1991

TOPIC: SUPPLIER VERIFICATION

ISSUE:

In the midst of ever evolving media reports portraying negative HME service, brought on in part by the existence of no barriers to entry to becoming an HME supplier, the HME Industry clearly recognizes the need to move in the direction of licensure and certification to differentiate quality and to consider other barriers to entry that establish basic business criteria.

In the current environment, supplier numbers are issued with little to no scrutiny of the applicant's basic business qualifications. Additionally, HME companies usually are not subject to state licensure laws, quality assurance standards or other similar criteria typically required of health organizations and professionals.

Given these shortcomings, focus in the current environment rests solely on rear end screening to eliminate the abusive activities and abusers of the system.

The following recommendations resulting from this conference focus on a front end screening program to establish baseline business standards as prerequisites to entry and involvement in the Medicare program.

RECOMMENDATION:

Recommended solutions created from a consensus of the workgroup include the following:

- I. Stated criteria which must be met to both become and remain qualified as an HME supplier.

The criteria, along with a brief explanation of how the information will be used, should be available to all supplier candidates prior to completion of an application for enrollment in the program, perhaps in the form of a Supplier Qualification packet. The supplier will be asked to attest to the information in the application and compliance with all stated criteria by completion of the enrollment/renewal application.

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Suggested criteria for enrollment are as follows:

- A. No prior exclusions from the Medicare/Medicaid program as a result of civil or criminal actions.
 - B. Compliance with all applicable state and federal licensure and regulatory agencies.
 - C. The supplier must maintain a physical facility, with both inventory and personnel on site.
 - D. Proof of adequate product/professional liability insurance.
 - E. Written maintenance and service procedures and protocols.
 - F. Written personnel/staffing standards and protocols.
 - G. Written procedures and protocols regarding record management.
 - H. Written safety and infection control protocols. for both employees and patients.
- II. Required disclosure of information that will assist the carrier in monitoring for potentially abusive practices.

Suggested information disclosure includes:

- Physician, hospital, nursing home ownership interests.
 - Type of products and services offered.
 - Sales/Marketing information/practices.
 - Pricing practices/policy.
-

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- III. A rigorous application to be administered uniformly for both new supplier applications as well as on an established renewal cycle.

Recommended content for development of a standardized supplier application is included as Attachment A.

This application should be administered uniformly for all HME companies that wish to become or remain a Medicare supplier.

The workgroup recommends that each approved supplier be required to reapply on a cyclical basis to remain qualified for participation in the program. A minimum two year renewal term is recommended for all suppliers, with the carrier maintaining the right to require more frequent renewals from select suppliers based on a high level of abusive performance or alleged problems, or at the request of HCFA or the OIG.

Signed attestation as to the accuracy and thoroughness of the submitted information, as well as signed agreement with stated criteria and conditions for approval, is recommended as an adjunct to the Application.

- IV. Required verification procedures to be performed routinely and uniformly prior to approval of both initial and renewal applications.

Equally as important as expanding the degree of information required to become qualified as an HME supplier, verification of the submitted data is absolutely imperative. Therefore, it is recommended that minimum verification procedures and protocols be established and compliance monitored to ensure validity of the screening process. This process could be administered by each carrier, by a national contractor or by HCFA.

Ideally, a system of cross referencing information among all program carriers is recommended. A program like UPIN could be used for administration of the application process on a national basis.

Recommended minimum verification procedures are also outlined in Attachment A. These procedures are not intended to be all inclusive and are recognized to require subjective review in some cases.

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It is recommended that consideration be given to mandatory on-site inspection based on the level of negative or questionable responses which cannot be verified otherwise, or based on randomly selected applications.

Per the attestation section of the application, it is recommended that the applicant attest to their understanding that the carrier (or other approval organization) has the right to require or perform on-site inspection at their discretion.

The above recommended barriers to entry represent a first step in the direction of purifying the HME marketplace -- both in terms of legitimizing competition and competitors, as well as stabilizing the reimbursement environment adversely impacted by system abuse. Coupled perhaps with additional standards of quality and accreditation opportunities, the HME Industry will become postured among its counterparts within the healthcare system to play a recognized significant role in the future of healthcare delivery in this country.

SUPPLIER VERIFICATION
HIDA CONSENSUS CONFERENCE
May 13-14, 1991

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

NAME AND LOCATION:

1. Supplier Name
2. Contact Person/Position at Business
to whom correspondence/questions should
be addressed.
3. Supplier Address
(Indicate complete street address.
P.O. Boxes not acceptable)
4. Is this property zoned for commercial
purposes?
5. Mailing/Billing Address
(if different from above)
6. Telephone Number(s) at both of the above
locations.
7. List all field/sales offices operating under
this provider number, with complete address
and telephone number.
8. Billing Agent if different from Supplier
(Complete name and address of each agent
used.)

Attachment A

VERIFICATION / COMMENT

Telephone contact to review clarity of information provided,
as well as to verify validity of number.

Verify with applicable local tax assessment organization.

Verify per above phone call.

Determine exact nature of relationship. If agent is another
supplier, closely examine ownership structure per Ownership
section.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

OTHER CARRIERS BILLED:

1. List any other Medicare carriers which are currently billed for any services (include name of carrier, supplier number and primary items for which they are billed).

Inquire of each listed carrier status of supplier performance and claim type to determine compliance with carrier jurisdiction rules.

TYPES OF PRODUCTS/SERVICES:

1. Which of the following products/services do you provide:

- ☐ Durable Medical Equipment
- ☐ Oxygen
- ☐ Ventilators
- ☐ Apnea Monitoring
- ☐ PEN
- ☐ O & P

2. Are Medicare items ordered by the beneficiary prior to the prescribing physician's prescription?

If so, are these inexpensive retail items bought across the counter?

Cross reference each indicated product/service to:

- submitted health professional licensure information.
- compliance with applicable state regulatory requirements, (e.g. FDA).

If response indicates beneficiary directed order, monitor for possible telemarketing abuses.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

SALES / MARKETING:

1. Are physicians, nurses, therapists or beneficiaries used for marketing purposes? If yes, describe.

Determine if nature of marketing strategy needs to be monitored for possible abuse.

2. If these individuals provide marketing services under contract, how are they compensated:

If response is percentage basis, warrants additional investigation and monitoring.

- ☐ % of Revenue generated
- ☐ % of Collections on Revenue generated
- ☐ Flat Fee (Not related to referrals)
- ☐ Other (please describe)

3. Do you conduct outgoing solicitation to :

If beneficiaries, review written guide for inappropriate tele-marketing practices (Waiver of coinsurance, non-medical necessity, etc.)

- ☐ Beneficiaries *
- ☐ Physicians
- ☐ Other Referral Sources

* If yes, please submit a copy of your written solicitation guide.

SUPPLIER VERIFICATION
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RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

4. For each sales representative employed,
please indicate:

- Name and address.
- Telephone number where can they can be reached.
- Assigned branch.
- States served.

(May be too burdensome to monitor this.)

5. Are orders received and processed outside of
this carrier jurisdiction?

If yes, review claim submission practices with multiple carriers to
determine compliance with carriers jurisdiction rules.

6. Are sales made through catalogs to
beneficiaries outside this carrier
jurisdiction?

a. Do you deliver these products from this
supplier address?

b. Do you subcontract with another supplier
for delivery of these products?

See below.

If yes, warrants additional investigation to determine validity of
supplier billing.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

PATIENT SET-UP/DELIVERY

1. Indicate information given to the beneficiary prior to or at the time of delivery:

- ☐ Teaching and training materials.
- ☐ Contract stating terms of rental or purchase.
- ☐ Patient Bill of Rights.
- ☐ Emergency contact procedures.
- ☐ Other (please specify).

Must have written policies.

2. How are beneficiary signatures obtained:

- ☐ in person
- ☐ over the phone
- ☐ by mail
- ☐ other (please explain)

Warrants further investigation if over the phone.

3. How are products delivered to beneficiaries:

- ☐ commercial or U.S. Postal service
- ☐ company delivered.
- ☐ picked up by beneficiary.

Use information to identify potential carrier jurisdiction issues.

4. Who completes medical necessity information on the Certificate of Medical Necessity:

- ☐ physician or agent.
- ☐ supplier.
- ☐ other (please explain).

The correct response.
Supplier not acceptable. (Refine based on current carrier instructions)
Suspect - investigate.

5. How long are patient/transaction specific documents retained?

Response should correspond to federal and state requirements.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

PRICING:

- | | |
|--|---|
| 1. Are Medicare and non-Medicare patients charged the same for identical services. If no, explain | If response is no, investigate to ensure government is not charged more. |
| 2. Do you inform the beneficiary of his/her responsibility for coinsurance? a. Is this communication written or verbal? b. When does this communication occur? | If no, indicates non compliance. Communication should be written. Preferably prior to or at time of delivery. |
| 3. Do you have a written procedure to review the beneficiaries desire to waive coinsurance? | Require written procedure. |
| 4. Percentage of coinsurance waived over the past twelve months (for renewal applications). | Excessive percentage warrants investigation. |
| 5. Do you have a system in place to adjust billed utilization to actual utilization for disposable supplies? | If not, cannot receive/maintain supplier number. |

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

OWNERSHIP:

1. Type of Business

- ☐ Corporation
- ☐ Partnership
- ☐ Sole Proprietorship

2. If incorporated, Date and State of Incorporation

Verify with applicable state.

3. Federal Tax Identification Number

Verify with applicable government agency.

4. Hospital based or affiliated?

5. Was company purchased? If so:

- a. Were the receivables purchased.
- b. Name of the former owner(s).
- c. Former name of company and address.
- d. Indicate carriers billed with corresponding provider numbers.

Cross reference to OIG or other applicable databases.

Inquire as to supplier performance/standing.

6. Please provide a complete list of company Officers, with corresponding Social Security Numbers for each.

Cross reference with applicable government agencies, other carriers and OIG.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

7. List the names of each owner, partner or other individual who has a financial interest in the company.

a. State the exact nature of the interest each individual holds (e.g. stock, loan).

b. Identify any of these individuals who is or has been a provider of Medicare services.

- Indicate exact name and address of the provider.

- Indicate the provider numbers under which each operates or has operated.

Cross reference to OIG or other applicable source.

8. Have any of the following individuals been the subject of any civil or criminal action with respect to services billed to Medicare, Medicaid or any other Insurance company?

___ any of the Officers listed above?

___ any of the Owners, partners or other individuals having a financial interest listed above?

___ any relatives of the Owners, partners or other individuals having a financial interest listed above?

___ any employees of the company?

___ any contract therapists, nurses or pharmacists?

If yes, provide explanation.

Warrants investigation.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

9. If the company is related (by common ownership or management) to any other organization that is also a provider of Medicare services, identify:

- a. exact name and address of related organization.
- b. relationship to the company and the nature of Medicare services they provide.
- c. name of the Medicare contractors that are billed and the provider numbers used for this purpose.

10. List name, specialty and license number of any physician, therapist or other licensed practitioner who is an employee, officer, or who has an ownership interest in the company. State exact function.

11. List name, specialty and license number of any physician, therapist or other licensed practitioner who is used on a consulting/contract basis. Specify exact function.

Cross reference to OIG or other applicable databases used to monitor potential abusive referrals.
(Must define "common ownership or management").

Cross reference to OIG or other applicable databases.
Monitor for potential abusive referrals.

Share information obtained with OIG as applicable.

Cross reference to OIG or other applicable databases.
Monitor for potential abusive referrals.

Share information obtained with OIG as applicable.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

OPERATIONS:

1. Is your company accredited by:

☐ JCAHO?
☐ CHAP?
☐ Other? (please specify.)

Date of accreditation: _____

2. Do you have written Quality Assurance protocols and procedures?

3. Is the company in compliance with all applicable state and federal regulatory requirements:

☐ DOT
☐ FDA
☐ OSHA
☐ Other, as applicable

4. Does the company own product inventory.
If no, please describe your arrangements for product distribution.

5. Are personnel onsite at the supplier address during stated hours of operation?
If no, please explain.

If yes, following questions warrant little review.

Must have.

Cross reference to products/services to determine applicable requirements.

Verify possible non-compliance with applicable state or federal agency.

If no, will not qualify for supplier number.

If no, will not qualify for supplier number.

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

| | | VERIFICATION / COMMENT |
|--------------------------|---|---|
| 6. | Do you provide (directly or by contract) 24 hour emergency telephone response service? | Required. |
| 7. | Does the company have a written policy regarding patient rights and responsibility? | Required (These policies do not get reviewed by the carrier, as in accreditation, but any business requiring a Medicare supplier number must have these written policies in place. Such written policy could be used in a lawsuit to establish the standard the company should have met). |
| 8. | Does the company have written infection control protocols (for both employees and patients)? | Required. |
| 9. | Does the company have written maintenance and service protocols, including training of service technicians. | Required. |
| 10. | Does the company have written personnel/staffing standards and protocols? | Required. |
| 11. | Does the company have written protocols and procedures regarding record management? | Required. |
| PLEASE ATTACH COPIES OF: | | |
| 1. | Current Professional License for each healthcare employee or contractor. | Cross reference to products/services to ensure all applicable are in place. |
| 2. | Pharmacy License, if applicable. | Verify standing with state board. |
| 3. | Occupational License, if applicable. | |
| 4. | Certificate of Product/Professional Liability Insurance. | Verify active coverage. |

RECOMMENDED SUPPLIER APPLICATION CONTENT
AND VERIFICATION PROCEDURES

VERIFICATION / COMMENT

SIGNATURES / ATTESTATION

1. Owner/President name and signature.
2. Attestation statement to include:
 - a. understand all information will remain confidential.
 - b. understand some or all of the information provided will be verified by the carrier, both prior to issuance of a provider number as well as on an ongoing basis as deemed appropriate. This may include onsite inspection.
 - c. attestation that information provided is accurate and complete.
 - d. understand that an updated application is required within 60 days if change in ownership or for addition of products services not included on initial or most recent application.
 - e. understand the supplier number may be suspended or repealed if false information is provided.



September 26, 1994

VIA FACSIMILE & U.S. MAIL

Ms. Penny Thompson
Office of Inspector General
Office of Evaluation & Inspections
Department of Health & Human Services
6325 Security Blvd., Rm. 1-D-16 OM
Baltimore, Maryland 21207

Dear Ms. Thompson:

Thank you for sending us an advance copy of the draft OIG report on oxygen services. We sent it to our members who manufacture oxygen products. Our comments are as follows:

1. Page 1 - Change life-supporting to supplemental oxygen (6th paragraph). Oxygen concentrators are considered non-life support devices by the FDA, they do provide supplemental oxygen.
2. Page 16 - Under "Establishing minimum requirements" section, HCFA may want to take into account use of Oxygen Concentration Status Indicators (OSCI). Two standards (ASTM 1464-93 and ISO 8359) will/do require the use of OCSI's on all concentrators. This may be a minimum requirement, so that absent an OCSI reimbursement for a concentrator would be less than for those units so equipped.

Please call me if you have any questions concerning these comments.

Sincerely,

Marcia Nusgart, R.Ph.
Director, Home Care

MN/bcj

Health Industry Manufacturers Association

1200 G STREET, N.W., SUITE 400

WASHINGTON, D.C. 20005-3814

(202) 783-8700

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AMERICAN ASSOCIATION FOR RESPIRATORY CARE
11030 Ables Lane, Dallas, TX 75229, 214/243-2272, Fax 214/484-2720

October 3, 1994

June Gibbs Brown
Department of Health & Human Services
Office of Inspector General
5250 Cohen Building
330 Independence Avenue S.W.
Washington, DC 20201

Dear Inspector General Brown:

The American Association for Respiratory Care (AARC), a professional association representing 37,000 respiratory care practitioners (RCPs), has reviewed the draft of the Inspector General's (IG) report "Oxygen Concentrator Services".

The AARC has, over the years, consistently stressed the critical importance of providing support services, in particular patient assessment, as a key component of home oxygen therapy. We are gratified that the IG's report has reached the same conclusion. Inconsistencies in providing support services among suppliers can no longer be permitted. The number of patients requiring home oxygen therapy is increasing, and will continue to increase as the population ages. The advancements in medical technology coupled with the financial pressures on hospitals to discharge pulmonary-compromised patients earlier results in a more fragile patient receiving oxygen therapy in the home.

COMMENTS:

While the AARC supports the recommendations of the IG's report, we are concerned about the methodology used in constructing this report. The sample size is very small, i.e., only 244 beneficiaries out of 220,371 oxygen therapy patients were surveyed. Such a small sample size could affect the statistical validity of the report. Furthermore, no mention was made of the geographical distribution or the "type" (i.e., national chain, small independent business, respiratory only, home infusion, etc.) of the 183 suppliers used within the report. These types of variations have an affect on survey outcomes and data collection. We note that the report acknowledges that 1991 data was used and stipulates that "concerned organizations have implemented improved standards of care since then". We believe that that point should be further emphasized, simply for the fact that so much change has occurred over the last three years in the home health care arena. We are also concerned that broad comparisons are made between the Veteran Administration's method of providing home oxygen therapy and the way Medicare program provides these services. Perhaps, the differences between the two programs should be emphasized.

In the Executive Summary, respiratory therapy is incorrectly referenced on Page i, paragraph 5, the line reading "...life sustaining respiratory therapy for patient...". The term "oxygen therapy" should be substituted. Respiratory therapy compromises more than just oxygen therapy, and can include, but is not limited to, such therapies as chest physiotherapy, mechanical ventilation, and aerosol therapy. The same incorrect reference is made in the introduction on Page 1, paragraph 5.

June Gibbs Brown
Office of Inspector General
Page Two
October 3, 1994

Page 13 - Third paragraph, last line - "credentialling" is misspelled.

Page 16 - Item #1 - we would urge you to specifically acknowledge the AARC, along with the references to JCAHO, CHAP, and NAMES. Much of the standards these organizations developed were based on the AARC's standards.

A key element in the education and clinical testing of a respiratory care practitioner is patient assessment. RCPs are the only professionals trained in all elements of respiratory care diagnosis, treatment, and therapy. Patient assessment of the home oxygen patient is an integral component in the delivery of proper therapy, as well as a safeguard in assuring only the appropriate equipment and services are rendered.

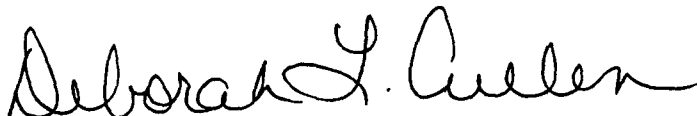
The FDA classifies home oxygen therapy equipment and related accessories as legend devices. Accordingly, home medical equipment (HME) providers must have a valid physician's prescription prior to dispensing such equipment. A device requiring a physician's prescription would likewise require consistent and systematically planned follow up to reduce the likelihood of compromising the patient's health and/or life through misuse or non-use.

Perhaps, another avenue in reaching the goal of enhanced patient services for home oxygen therapy would be to amend the current Medicare certificates of medical necessity (CMN) for oxygen by requiring more patient assessment procedures.

It is apparent to us that inconsistencies regarding appropriate patient services for home oxygen patients will abound until minimum service standards are required by Medicare. It is inherently unfair and medically unacceptable for Medicare beneficiaries to be placed in a situation where critical oxygen services are left strictly to chance.

The AARC strongly endorses the recommendations proposed in the IG's report, "Oxygen Concentrator Services".

Sincerely,

A handwritten signature in black ink, reading "Deborah L. Cullen". The signature is fluid and cursive, with the first name "Deborah" being more prominent and the last name "Cullen" following in a similar style.

Deborah L. Cullen, EdD, RRT
President, AARC

DLC/jr